AZIENDA OSPEDALIERA UNIVERSITARIA

DELIBERAZIONE DELLA DIRETTRICE GENERALE

OGGETTO:

L'Estensore:

Proposta N. Del

Allegati:

Numero imputazione spesa Imputazioni di spesa

Data imputazione spesa

Si autorizza l'imputazione della spesa sul conto e l'esercizio indicati entro il limite del budget annuale assegnato al centro di costo richiedente.

Nulla osta, in quanto conforme alle norme di contabilità.
Il Direttore Area Economica Finanziaria

Parere
Il Direttore Amministrativo

La Direttrice Generale
Dott.ssa Maria Grazia Furnari

Parere
Il Direttore Sanitario

La Direttrice Generale dell'AOUP "Paolo Giaccone" di Palermo, Dott.ssa Maria Grazia Furnari, nominata con D.P. n.324 serv.1°/S.G. del 21 giugno 2024 e assistita dal segretario verbalizzante adotta la seguente delibera sulla base della proposta di seguito riportata.

Il Segretario verbalizzante

AZIENDA OSPEDALIERA UNIVERSITARIA

LA DIRETTRICE GENERALE

PRESO ATTO che presso l'AIFA è stato istituito il Centro di Coordinamento nazionale dei Comitati Etici Territoriali e ricostituito con il Decreto del Ministro della Salute del 27/05/2021, garante dell'omogeneità delle procedure e del rispetto dei termini temporali;

PRESO ATTO dell'entrata in vigore in data 31/01/2022 del nuovo Regolamento (EU) n. 536/2014 del Parlamento Europeo sulla sperimentazione clinica di medicinali per uso umano;

VISTI il Decreto 26 gennaio 2023 recante: "individuazione di quaranta comitati etici territoriali (di seguito indicato con DM 40 CET);

il Decreto del 27 gennaio 2023, del Ministero della Salute recante misure relative all'individuazione e competenze dei Comitati Etici Territoriali;

il Decreto 30.01.2023 recante: "definizione dei criteri per la composizione e il funzionamento dei comitati etici territoriali";

PRESO ATTO che, con delibera n. 916 del 30/06/2023 e ss.mm.ii., è stato istituito il CET (Comitato Etico Territoriale) e la Segreteria Tecnico Scientifica, in applicazione al Decreto Regionale n. 541/2023;

che con delibera n. 1072 del 03.08.2023 è stato recepito il D.A. dell'Assessorato Salute RS n. 746 del 25.07.2023, successivamente integrato dalla nota n. 57116 "corretta applicazione art. 2 commi 5 e 6";

VISTA la delibera n. 513 del 26/05/2025 di sottoscrizione della Convenzione economica tra l'AOUP e per essa l'UOC di Ematologia e la Società ICON Clinical Research Limited che autorizza l'avvio della Sperimentazione clinica su medicinali dal titolo: "Studio di fase 3,in aperto, randomizzato, per confrontare l'efficacia e la sicurezza di odronextamab (REGN1979), un anticorpo bispecifico Anti-CD3 in combinazione con chemioterapia rispetto a rituximab in

combinazione con chemioterapia in partecipanti con linfoma follicolare precedentemente non trattati (OLYMPIA-2) Protocollo: R1979-ONC-2075 - EU CT 2022-502113-28-00 Sperimentatore: Prof.ssa Salvatrice Mancuso;

DATO ATTO che in data 28/01/2025 il Promotore ha ricevuto il Provvedimento AIFA che autorizza l'SM-1 al Protocollo di Studio che modifica l'art. 6 corrispettivo paziente e l'allegato A – Budget;

VISTO l'Emendamento 1 sottoscritto e allegato come parte sostanziale e integrante, alla Convenzione tra l'AOUP e per essa l'UOC di Ematologia e la Società ICON Clinical Research Limited per effettuare la Sperimentazione Clinica su medicinali Protocollo: R1979-ONC-2075;

Per i motivi in premessa citati che qui si intendono ripetuti e trascritti

DELIBERA

Di prendere atto dell' Emendamento 1, sottoscritto e allegato come parte sostanziale e integrante alla convenzione tra l'AOUP Paolo Giaccone e per essa l'UOC di Ematologia e la Società ICON Clinical Research Limited, per la conduzione della Sperimentazione su medicinali dal titolo: "Studio di fase 3,in aperto, randomizzato, per confrontare l'efficacia e la sicurezza di odronextamab (REGN1979), un anticorpo bispecifico Anti-CD3 in combinazione con chemioterapia rispetto a rituximab in combinazione con chemioterapia in partecipanti con linfoma follicolare precedentemente non trattati (OLYMPIA-2) Protocollo: R1979-ONC-2075". Protocollo: R1979-ONC-2075 - EU CT 2022-502113-28-00 Sperimentatore: Prof.ssa Salvatrice Mancuso;

di prendere atto che i proventi derivanti dallo Sponsor per la conduzione dello Studio, verranno ripartiti in conformità all'art. 4 - Aspetti economici- finanziari – del Regolamento Aziendale disciplinante gli aspetti procedurali, amministrativi ed economici degli studi Osservazionali, delle Sperimentazioni cliniche, dei Dispositivi Medici e delle Iniziative di Ricerca afferenti all'AOUP approvato con Delibera n. 362 dell' 04/04/2025.

EMENDAMENTO n. 1 AL CONTRATTO PER LA CONDUZIONE DELLA SPERIMENTAZIONE CLINICA SU MEDICINALI **"Studio di fase 3, in aperto, randomizzato per confrontare l'efficacia e la sicurezza di odronextamab (REGN1979), un anticorpo bispecifico Anti-CD20 x Anti-CD3 in combinazione con chemioterapia rispetto a rituximab in combinazione con chemioterapia in partecipanti con linfoma follicolare precedentemente non trattati (OLYMPIA-2)"**	**AMENDMENT No. 1 TO THE AGREEMENT FOR THE CONDUCT OF A CLINICAL TRIAL ON MEDICINAL PRODUCTS** **"A Phase 3, Open-Label, Randomized Study to Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20 x Anti-CD3 Bispecific Antibody, Combined with Chemotherapy Versus Rituximab Combined with Chemotherapy in Previously Untreated Participants with Follicular Lymphoma (OLYMPIA-2)"**
Questo emendamento ("**Emendamento n. 1**") viene stipulato ed entra in vigore a partire dal 21 maggio 2025 data di firma del contratto iniziale (di seguito "**Data di Efficacia**").	This amendment ("**Amendment No. 1"**) is made and enters into effect starting from 21 May 2025, the date of signing of the initial agreement (hereinafter "**Effective Date**")
TRA:	BETWEEN:
ICON Clinical Research Limited, con sede legale in South County Business Park, Leopardstown, Dublino 18, Irlanda, P. IVA n. IE 8201978R, in persona del procuratore delegato alla firma del presente contratto (di seguito "**CRO**"), la quale agisce in nome e per conto di **Regeneron Pharmaceuticals, Inc.**, con sede legale in 777 Old Sawmill River Road Tarrytown, NY 10591, Stati Uniti d'America (di seguito "**Promotore**"), in	**ICON Clinical Research Limited**, with registered office in South County Business Park, Leopardstown, Dublin 18, Ireland, VAT No. IE 8201978R, through its attorney appointed to sign this agreement (hereinafter "**CRO**"), acting in the name and on behalf of **Regeneron Pharmaceuticals, Inc.**, with registered office at 777 Old Sawmill River Road Tarrytown, NY 10591, United States of America (hereinafter "**Sponsor**"),

forza di idonea procura conferita in data 18 settembre 2023,	pursuant to an appropriate power of attorney conferred on 18 September 2023,
E	AND
AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO "PAOLO GIACCONE" DI PALERMO (d'ora innanzi l'"**Ente**"), con sede legale in Palermo (Italia), Via del Vespro 129, C.F. e P. IVA n. 05841790826, in persona del Legale Rappresentante, Dott.ssa Maria Grazia Furnari, in qualità di Direttrice Generale.	**AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO "PAOLO GIACCONE" DI PALERMO** (hereinafter the "**Institution**"), with registered office in Palermo (Italy), Via del Vespro 129, Tax ID and VAT no. 05841790826, through its Legal Representative, Dr. Maria Grazia Furnari, in the capacity of General Director.
indicati individualmente come "**Parte**" o congiuntamente come "**Parti**" nel contesto del presente Emendamento n. 1.	Individually referred to as a "**Party**" or collectively as the "**Parties**" in the context of this Amendment No. 1.
PREMESSO CHE	**WHEREAS**
(i) Le Parti hanno stipulato un contratto di sperimentazione clinica in data 21 maggio 2025 (di seguito "**Contratto**") per la conduzione di una sperimentazione clinica dal titolo "Studio di fase 3, in aperto, randomizzato per confrontare l'efficacia e la sicurezza di odronextamab (REGN1979), un anticorpo bispecifico Anti-CD20 x Anti-CD3 in combinazione con chemioterapia rispetto a rituximab in combinazione con chemioterapia in	(i) The Parties entered into a clinical trial agreement on 21 May 2025 (hereinafter "**Agreement"**) for the conduct of a clinical trial entitled "A Phase 3, Open-Label, Randomized Study to Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20x Anti-CD3 Bispecific Antibody, Combined with Chemotherapy Versus Rituximab Combined with Chemotherapy in Previously Untreated Participants with

partecipanti con linfoma follicolare precedentemente non trattati (OLYMPIA-2)" (di seguito "**Sperimentazione**"), sotto la responsabuilità del Prof.ssa Salvatrice Mancuso (di seguito "**Sperimentatore Principale**"); le Parti desiderano, pertanto, modificare alcuni termini del Contratto; l'emendamento è stato approvato il 29 gennaio 2025, data del caricamento del provvedimento di autorizzazione nazionale AIFA sul portale UE di cui all'art. 80 del che include il parere emesso dal Comitato Etico Territoriale.	Follicular Lymphoma (OLYMPIA-2)**"** (hereinafter "**Trial**") under the responsibility of Prof. Salvatrice Mancuso (hereinafter "**Principal Investigator**"); the Parties therefore wish to amend some terms of the Agreement; the amendment was approved on 29 January 2025, the date on which the AIFA national authorization provision was uploaded to the EU portal as per Art. 80, along with the opinion issued by the Territorial Ethics Committee.
PERTANTO, IN CONSIDERAZIONE DELLE PREMESSE E DELLE RECIPROCHE PROMESSE E IMPEGNI QUI CONTENUTI, LE PARTI CONVENGONO QUANTO SEGUE:	NOW, THEREFORE, IN CONSIDERATION OF THE PREMISES AND MUTUAL PROMISES AND UNDERTAKINGS HEREIN CONTAINED, THE PARTIES HERETO AGREE AS FOLLOWS:
– Le Parti desiderano ora modificare il Contratto secondo i termini e le condizioni del presente Emendamento n. 1 in ragione dell'emendamento n 2 al Protocollo di Sperimentazione v.3 Globale datato 23 agosto 2024 (di seguito "**PA2**"), che si traduce in:	– The Parties now wish to amend the Agreement as per the terms and conditions of this Amendment No. 1 due to the amendment N 2 to the Trial Protocol v.3 Global dated 23 August 2024 (hereinafter "**PA2**"), which results in:

- aggiunta di regimi di dosaggio da valutare nella parte di ottimizzazione della dose (Parte 1B) della Sperimentazione; - modifica del programma delle visite; - modifica nelle procedure da condurre; - modifica nel disegno della Sperimentazione che implica modifiche del budget. Le Parti desiderano ora modificare il Contratto secondo i termini e le condizioni del presente Emendamento n. 1 al fine di: - modificare l'Art. 6 – Corrispettivo, paragrafo 6.1, per adeguare il costo per paziente in base ai cambiamenti apportati al budget secondo il PA2; - sostituire l'Allegato A e Allegato A-1 con un nuovo Allegato A e un nuovo Allegato A-1, in virtù dei cambiamenti apportati al budget secondo il PA2.	- addition of dosing regimens to be evaluated in the dose-optimization part (Part 1B) of the Trial; - change to the schedule of visits; - change to the procedures to be conducted; - change to the Trial design which results in changes to the budget. The Parties now wish to amend the Agreement as per the terms and conditions of this Amendment No. 1, to: - amend Art. 6 – Consideration, paragraph 6.1, to adjust the cost per patient in virtue of the changes made to the budget according to PA2; - replace the Annex A and Attachment A-1 with a new Annex A and a new Attachment A-1, due to the changes made to the budget according to PA2.
Le Parti si accordano come segue.	The Parties agree as follows.
1. GENERALE	**1. GENERAL**
1.1 Nel presente Emendamento n. 1, salvo esplicitamente dichiarato nel presente	1.1 In this Amendment No. 1, unless expressly stated herein, the defined terms shall have

documento, i termini definiti hanno lo stesso significato enunciato nel Contratto.	the same meaning as in the Agreement.
1.2 Le Parti convengono che i termini nel presente Emendamento n. 1 e tutti gli altri termini e condizioni resteranno in vigore ed efficacia secondo i loro termini attuali nell'ambito del Contratto. In caso di eventuali incoerenze tra i termini del presente Emendamento n. 1 e il Contratto, prevarranno i termini del presente Emendamento n. 1.	1.2 The Parties agree that the terms in this Amendment No. 1 and all other terms and conditions shall remain in full force and effect as per the current terms of the Agreement. In the event of any discrepancy between this Amendment No. 1 and the Agreement, the terms of this Amendment No. 1 shall prevail.
2. DISPOSIZIONI MODIFICATE	**2. AMENDED PROVISIONS**
2.1 A partire dalla Data di Efficacia, le Parti concordano di modificare: - l'articolo 6 - Corrispettivo, paragrafo 6.1 del Contratto con le seguenti disposizioni modificate: "Il corrispettivo pattuito, preventivamente valutato dall'Ente, per paziente eleggibile, valutabile e che abbia completato il trattamento sperimentale secondo il Protocollo e per il quale sia stata compilata validamente la relativa CRF/eCRF (CRF elettronica), comprensivo di tutte le spese sostenute dall'Ente per l'esecuzione della	2.1 From the Effective Date, the Parties agree to amend: - article 6 – Consideration, paragraph 6.1 of the Agreement with the following amended provisions: "The agreed consideration, previously assessed by the Institution, for an eligible, assessable patient who has completed the Trial treatment according to the Protocol and for whom the relevant CRF/eCRF (electronic CRF) has been validly completed, inclusive of all expenses incurred by the Institution for the conduct of the Trial and the costs of all related

Sperimentazione e dei costi di tutte le attività ad essa collegate, è pari a:	activities, is equal to:
• **€ 45.393,00** (qquarantacinquemilatrecentonovantatrè/00) + (IVA se applicabile) per paziente nella Parte 1A, Parte 1B Regime I, Parte 2 Braccio B;	• **€ 45,393.00** (forty-five thousand three hundred ninety-three/00) + VAT (if applicable) per patient in Part 1A, Part 1B Regimen I, Part 2 Arm B;
• **€ 41.667,00** (quarantunomilaseicentosessantasette/00) + (IVA se applicabile) per paziente nella Parte 1B Regime II	• **€ 41,667.00** (forty-one thousand six hundred and sixty-seven/00) + VAT (if applicable) per patient in Part 1B Regimen II;
• **€ 32.654,00** (trentaduemilaseicentocinquantaquattro/00) + (IVA se applicabile) per paziente nella Parte 2 Braccio A;	• **€ 32,654.00** (thirty-two thousand six hundred fifty-four/00) + VAT (if applicable) per patient in Part 2 Arm A;
• **€ 27.680,00** (ventisettemilaseicentoottanta/00) + (IVA se applicabile) per paziente nel Braccio C (R-CHOP),	• **€ 27,680.00** (twenty-seven thousand six hundred eighty/00) + VAT (if applicable) per patient in Arm C (R-CHOP),
come meglio dettagliato nel budget qui allegato (Allegato A)."	as better detailed in the budget attached hereto (Annex A)."
- L'Allegato A – Budget e l'Allegato A-1 (budget dettagliato) sono sostituiti dall'Allegato A e dall'Allegato A-1 (budget dettagliato) aggiornati, allegati al presente Emendamento n. 1.	- Annex A – Budget and Attachment A-1 (detailed budget) are replaced with the updated Annex A and Attachment A-1 (detailed budget), attached to this Amendment No. 1.

AD ATTESTAZIONE DI QUANTO SOPRA, le Parti hanno provveduto a far sottoscrivere il presente Emendamento n. 1 dai rispettivi rappresentanti debitamente autorizzati con firma digitale ai sensi dell'art. 24 del D. Lgs. 82/2005, giusta la previsione di cui all'art. 15, comma 2bis della Legge n. 241/1990, come aggiunto dall'art. 6, D.L. 18 ottobre 2012, n. 179, convertito in Legge 17 dicembre 2012 n. 22. L'imposta di bollo è assolta in modo virtuale da ICON Holdings Clinical Research International Limited, con sede legale in Via Benigno Crespi 19, 20159 Milano, Italia, affiliata italiana della CRO, ex art. 15 del D.P.R. 642 del 1972 (Autorizzazione Agenzia delle Entrate di Milano protocollata in data 14 giugno 2023 sul Registro Ufficiale con il numero 203622).	IN WITNESS WHEREOF, the Parties have, by their duly empowered representatives, digitally signed this Amendment No. 1 in accordance with Article 24 of Legislative Decree 82/2005, in accordance with the provisions of Article 15 paragraph 2bis of Law 241/1990 as supplemented by Article 6, Decree Law 18 October 2012, No. 179, converted into Law No. 22 of 17 December 2012. Stamp duty is paid electronically by ICON Holdings Clinical Research International Limited, with registered office in Via Benigno Crespi 19, 20159 Milan, Italy, Italian affiliate of the CRO, pursuant to art. 15 of the Presidential Decree (D.P.R.) 642 of 1972 (Authorization of the Revenue Agency of Milan registered on 14 June 2023 on the Official Register with number 203622).
Resto della pagina lasciato intenzionalmente in bianco - Segue la pagina delle firme	*Remainder of the page intentionally left blank – signatures page follows*

La CRO per il Promotore/The CRO for the Sponsor

Il Procuratore Delegato/The delegated attorney

Dott./Dr. Francesco Falcicchio

Firmato digitalmente/Digitally signed

Per l'Ente/For the Institution

AOUP Paolo Giaccone

La Direttrice Generale/The General Director

Dott.ssa/Dr. Maria Grazia Furnari

Firmato digitalmente/Digitally signed

ALLEGATO A – BUDGET	**ANNEX A – BUDGET**
ONERI E COMPENSI	**FEES AND CONSIDERATIONS**
Parte 1 - Oneri fissi e Compenso per paziente coinvolto nella Sperimentazione	**Part 1 - Fixed fees and Considerations per patient involved in the Trial**
- Fornitura del/i Medicinale/i Sperimentale/i e/o di ogni altro materiale in sperimentazione o necessario allo svolgimento della stessa affinché non vi sia aggravio di costi a carico del Servizio Sanitario Nazionale (kit diagnostici, dispositivi medici, ecc.).	- Provision of the Investigational Medicinal Product(s) and/or any other Trial materials or materials required to conduct the Trial, so as to ensure that there are no additional costs incurred by the National Health Service (diagnostic kits, medical devices, etc.).
- Compenso lordo a paziente completato coinvolto nella Sperimentazione: • **€ 45.393,00** (qquarantacinquemilatrecentonovantatrè/00) + (IVA se applicabile) per paziente nella Parte 1A, Parte 1B Regime I, Parte 2 Braccio B; • **€ 41.667,00** (quarantunomilaseicentosessantasette/00) + (IVA se applicabile) per paziente nella Parte 1B Regime II • **€ 32.654,00** (trentaduemilaseicentocinquantaquattro/00) + (IVA se applicabile) per paziente nella Parte 2	- Gross Consideration per completed patient involved in the Trial: • **€ 45,393.00** (forty-five thousand three hundred ninety-three/00) + VAT (if applicable) per patient in Part 1A, Part 1B Regimen I, Part 2 Arm B; • **€ 41,667.00** (forty-one thousand six hundred and sixty-seven/00) + VAT (if applicable) per patient in Part 1B Regimen II; • **€ 32,654.00** (thirty-two thousand six hundred fifty-four/00) + VAT (if applicable) per patient in Part 2 Arm A;

Braccio A; • **€ 27.680,00** (ventisettemilaseicentoottanta/00) + (IVA se applicabile) per paziente nel Braccio C (R-CHOP).	• **€ 27,680.00** (twenty-seven thousand six hundred eighty/00) + VAT (if applicable) per patient in Arm C (R-CHOP),
- Compenso per screening failure: si faccia riferimento alla sezione “Termini di Pagamento”. - Compenso per visita non programmata: si faccia riferimento alla sezione “Termini di Pagamento”.	- Fee for screening failures: please refer to section “Payment Terms”. - Fee for unscheduled visits: please refer to section “Payment Terms”.
- Fasi economiche intermedie (nel caso in cui i pazienti non completino l’iter sperimentale): si faccia riferimento all’Allegato A-1.	- Interim financial phases (if patients do not complete the Trial procedure): please refer to Attachment A-1.
- Tutti i costi rimborsabili relativi alla Sperimentazione, inclusi quelli coperti dal contributo per paziente coinvolto nella Sperimentazione, non comporteranno aggravio di costi a carico del Servizio Sanitario Nazionale (ad es. non vi sono prestazioni aggiuntive, gli esami strumentali e di laboratorio sono di tipo routinario per i pazienti in Sperimentazione, oppure gli esami strumentali sono di tipo routinario per i pazienti in Sperimentazione e quelli di laboratorio verranno effettuati con kit diagnostici forniti dal Promotore, oppure gli esami di laboratorio verranno effettuati	- All reimbursable Trial-related costs, including those covered by the fee per patient involved in the Trial, shall not entail any additional costs to be paid by the National Health Service (e.g. there are no additional services, the diagnostic and laboratory tests are routine for Trial patients, or the diagnostic tests are routine for Trial patients and laboratory tests will be performed with diagnostic kits provided by Sponsor, or laboratory tests will be performed in a single external centralised laboratory, at the expense of the Sponsor).

presso un unico laboratorio centralizzato esterno, a carico del Promotore).	
Parte 2 - Indennità per i pazienti e accompagnatori coinvolti nella Sperimentazione:	**Part 2 - Reimbursement for patients and carers involved in the Trial:**
- Si fa rinvio al modello "Indennità per i partecipanti alla Sperimentazione", incluso nel dossier della domanda ai sensi del Regolamento, da intendersi richiamato nel presente Contratto come sua parte integrante e sostanziale.	- Please refer to "Consideration for Trial participants" template, included in the application dossier pursuant to Regulation, to be understood to be recalled by this Agreement as an integral and substantial part of it.
LIQUIDAZIONE E FATTURE	**SETTLEMENT AND INVOICES**
- Il compenso deve essere liquidato entro 45 (quarantacinque) giorni dalla ricezione della fattura.	- The fee must be paid within 45 (forty-five) days from receipt of the invoice.
- La fattura deve essere emessa con cadenza prevista trimestrale secondo quanto maturato nel periodo di riferimento, sulla base di apposita richiesta di emissione fattura da parte del Promotore.	- The invoice must be issued on an expected quarterly basis according to the amount accrued during the relevant period, on the basis of a specific request for the issuance of the invoice by the Sponsor.
Budget e termini di pagamento	**Budget and Payment Terms**
Il Promotore fornisce un finanziamento per la	Sponsor provides funding for Institution's

partecipazione dell'Ente alla presente Sperimentazione come riportato nella tabella del budget, allegata di seguito (di seguito "**Budget**" o "**Allegato A-1**"). I pagamenti dovuti ai sensi del presente Contratto sono pagamenti addizionali a carico del Promotore, che saranno corrisposti dalla CRO una volta che la CRO li avrà ricevuti dal Promotore. La CRO corrisponderà i pagamenti per i servizi prestati dall'Ente al beneficiario (di seguito "**Beneficiario**") di seguito indicato come segue:	participation in this Trial as identified in the budget table, attached below (hereinafter "**Budget**" or "**Attachment A-1**"). Payments due under this Agreement are pass-through payments from Sponsor that will be sent by the CRO after such payments are received by the CRO from Sponsor. The CRO shall forward payments for services performed by Institution to the payee (hereinafter "**Payee**") identified below as follows:
A. <u>PAGAMENTO DI AVVIAMENTO</u>: Il Beneficiario riceverà un pagamento di avviamento una tantum non rimborsabile (come indicato nell'Allegato A-1). <u>Nota:</u> Il pagamento di avviamento sarà effettuato al ricevimento di una fattura una volta completata una visita di inizio Sperimentazione presso l'Ente, a condizione che il Promotore abbia ricevuto i seguenti documenti: (a) Contratto per Sperimentazione clinica pienamente perfezionato; (b) pagina delle firme del Protocollo firmata; (c) Site Information Form firmato; (d) curricula vitae dello Sperimentatore Principale e di tutti i Co-Sperimentatori; (e) approvazione del	**A. <u>START-UP PAYMENT</u>:** The Payee shall receive a one-time non-refundable start-up payment (as listed in Attachment A-1). <u>Note:</u> Start-Up Payment will be made upon receipt of an invoice when a site initiation visit has been completed at the Institution provided that the following documents have been received by Sponsor: (a) fully executed Clinical Trial Agreement; (b) signed Protocol signature page; (c) signed Site Information Form; (d) Curricula Vitae for the Principal Investigator and all Co-Investigators; (e) Ethics Committee approval of Protocol; (f) Ethics Committee approval of subject Informed Consent Form;

Protocollo da parte del Comitato Etico; (f) approvazione del modulo di consenso informato del soggetto da parte del Comitato Etico; e (g) elenco dei membri con diritto di voto del Comitato Etico. Il pagamento di avviamento includerà, a titolo esemplificativo e non esaustivo, la revisione del Protocollo, la formazione del personale della Sperimentazione, la preparazione e la presentazione al Comitato Etico insieme a tutte le altre mansioni amministrative che devono essere espletate prima dell'arruolamento.	and (g) list of Ethics Committee voting members. Start-up payment should include but are not limited to Protocol review, Trial staff training, Ethics Committee preparation and submission along with any other administrative tasks which must occur prior to enrollment.
B. <u>PAGAMENTI PER I SOGGETTI PARTECIPANTI ALLA SPERIMENTAZIONE</u>: Il Beneficiario riceverà i pagamenti basati sulle visite riportati nell'Allegato A-1, dove figurano tutti i costi associati alla Sperimentazione, incluse, a titolo esemplificativo ma non esaustivo, le spese generali, e il rimborso dei pazienti, ecc. Durante la conduzione della Sperimentazione, i pagamenti successivi pari all'85% del costo per visita saranno corrisposti con cadenza trimestrale per	**B. <u>TRIAL SUBJECT PAYMENTS</u>**: The Payee shall receive visit-based payments as listed in Attachment A-1 which shall include all costs associated with the Trial, including, without limitation, overhead, patient reimbursement etc. During the performance of the Trial, subsequent payments of 85% of the per visit cost will be paid quarterly for each qualified Trial subject who has completed the respective visit, after respective data are entered into Electronic Data Capture (hereinafter "**EDC**"). Trial

ciascun soggetto partecipante alla Sperimentazione idoneo che abbia completato la rispettiva visita, dopo che i rispettivi dati siano stati inseriti nel sistema elettronico di acquisizione dei dati (Electronic Data Capture, di seguito "**EDC**"). Il responsabile del monitoraggio della Sperimentazione o l'incaricato del Promotore possono verificare alla fonte l'avvenuto inserimento nell'EDC in occasione di una visita presso il Centro di Sperimentazione programmata successivamente. La riconciliazione del pagamento sarà effettuata al termine della Sperimentazione in occasione del Pagamento finale. "Soggetto Partecipante alla Sperimentazione Completato": si riterrà che tutti i soggetti partecipanti alla Sperimentazione abbiano completato la Sperimentazione se si saranno sottoposti a tutte le procedure e valutazioni di follow-up in occasione della Visita di Fine Trattamento.	monitor or Sponsor designee may source verify such EDC entry at a later scheduled Trial Site visit. Payment reconciliation will be performed at the end of the Trial against Final Payment. "Completed Trial Subject": all Trial subjects will be considered to have completed the Trial upon completion of follow up assessment and procedures at the End of Treatment Visit.
C. **MANCATI SUPERAMENTI DELLO SCREENING:** I Mancati Superamenti dello Screening (come definiti di seguito) saranno rimborsati al 100% del valore della Visita di	C. **SCREEN FAILURES:** Screen Failures (as defined below) will be reimbursed at 100% of Screening Visit value in Attachment A-1 per Screen Failure for up to a maximum of 1

screening di cui nell'Allegato A-1 per ogni Mancato Superamento dello Screening sino a un massimo di 1 Mancato Superamento dello Screening ogni 3 soggetti partecipanti alla Sperimentazione randomizzati. Il Beneficiario verrà rimborsato per ogni procedura completata durante la visita. Il Beneficiario riceverà l'85% del pagamento del Mancato Superamento dello Screening per tale Superamento dello Screening dopo l'inserimento dei dati nel sistema EDC; il restante 15% a cui ha diritto sarà sbloccato in conformità alla Sezione D "Pagamenti Finali". Per "Mancato Superamento dello Screening" si intende il caso di un soggetto partecipante alla Sperimentazione che abbia firmato il modulo di consenso informato ma che non abbia soddisfatto i criteri di inclusione/esclusione durante la fase di screening, oppure che abbia firmato il modulo di consenso informato e soddisfi i criteri di inclusione/esclusione ma non sia stato randomizzato. Nessun pagamento verrà corrisposto per soggetti partecipanti alla Sperimentazione, se ve ne sono, che siano	Screen Failures for every 3 Trial subjects randomized. Payee will be reimbursed for each procedure completed during the visit. Payee shall receive 85% of the Screen Failure payment for such Screen Failure, after data are entered into EDC; the remaining 15% entitlement is to be released according to Section D "Final Payments". A "Screen Failure" refers to a Trial subject who has signed the Informed Consent Form but failed to meet the inclusion/exclusion criteria during the screening phase or who has signed Informed Consent Form, meets the inclusion/exclusion criteria, but was not randomized. No payment will be made for Trial subjects, if any, who are inappropriately or improperly screened. Payee must obtain prior written approval from Sponsor to be reimbursed for more than 3 Screen Failures.

sottoposti allo screening in modo inadeguato o inappropriato. Per poter ottenere il rimborso di più di 3 Mancati Superamenti dello Screening, il Beneficiario dovrà ottenere il previo consenso per iscritto del Promotore.	
D. **PAGAMENTI FINALI:** Alla conclusione dell'intera Sperimentazione (i dati sono stati ricevuti da tutti i centri di Sperimentazione, tutte le richieste di chiarimento sui dati hanno ricevuto risposta, la banca dati è stata chiusa), il Promotore o il suo incaricato dovrà eseguire una riconciliazione finale del restante 15% a cui ha diritto il Beneficiario sull'importo totale per soggetto partecipante alla Sperimentazione, maturato sulla base del totale quivi stabilito e approssimativamente il 15% dell'importo totale maturato in relazione ai Mancati Superamenti dello Screening e ai pagamenti già effettuati.	**D.** **FINAL PAYMENTS:** At the conclusion of the Trial as a whole (data received from all Trial Sites, all queries resolved, database locked), Sponsor or Sponsor designee shall perform a final reconciliation of Payee's remaining 15% entitlement of the total per Trial subject amount accrued based on the total set forth herein and approximately 15% of the total amount accrued in connection with Screen Failures and payments made to date.
E. **VISITA DI INTERRUZIONE ANTICIPATA**: La visita di interruzione anticipata sarà pagata per procedura in base alle singole procedure elencate nell'Allegato A-1. Il Promotore tramite la CRO pagherà l'Ente entro	**E.** **EARLY TERMINATION VISITS**: Early Termination visit will be paid per procedure based on the individual procedures listed in Attachment A-1. Sponsor through the CRO will pay Institution within forty-five (45) days

quarantacinque (45) giorni dal ricevimento di una fattura dettagliata non contestata con relativa documentazione di supporto per la/e procedura/e eseguita/e.	of receipt of an undisputed itemized invoice with supporting documentation of procedure(s) performed.
F. <u>SPESE DI FARMACIA:</u> Le spese di farmacia saranno pagate in seguito al ricevimento di una fattura dettagliata, come stabilito nell'Allegato A-1. La CRO pagherà il Beneficiario entro 30 (trenta) giorni dal ricevimento di una fattura dettagliata non contestata. Tali spese includeranno tutti i costi associati alla farmacia, incluso, senza limitazioni, l'avviamento, la conservazione del farmaco, la dispensazione e la rendicontazione, il mantenimento annuale e la chiusura.	**F. <u>PHARMACY FEES:</u>** Pharmacy fees shall be paid upon receipt of an itemized invoice as defined in Attachment A-1. The CRO will pay Payee within 30 (thirty) days of receipt of an undisputed itemized invoice. Such fees shall include all cost associated with the pharmacy, including, without limitation, setup, drug storage, dispensing and accountability, annual maintenance and close-out.
G. <u>SPESE PER LA CONSERVAZIONE/ARCHIVIAZIONE DEI DOCUMENTI</u>: Il Beneficiario riceverà un compenso una tantum per la conservazione della documentazione per 25 (venticinque) anni e il Promotore pagherà il Beneficiario entro quarantacinque (45) giorni dalla ricezione di una fattura dettagliata non	**G. <u>RECORD RETENTION/ARCHIVING FEE</u>**: The Payee shall receive a one-time fee for the record retention for 25 (twenty-five) years and Sponsor will pay Payee within forty-five (45) days of receipt of an undisputed itemized invoice as defined in Attachment A-1.

contestata, come stabilito nell'Allegato A-1.	
H. <u>RIMBORSO DELLE SPESE DI VIAGGIO DEL SOGGETTO:</u>	**H. <u>SUBJECT TRAVEL REIMBURSEMENT:</u>**
La CRO rimborserà il Beneficiario in conformità all'Allegato A-1 per le ragionevoli spese di viaggio via terra e i pernottamenti/vitto sostenuti dai soggetti partecipanti alla Sperimentazione in relazione alla loro partecipazione alla Sperimentazione. Il Beneficiario deve emettere fatture alla CRO per tali spese, e deve includere le ricevute per voci quali pasti, chilometraggio, pedaggi, parcheggio e altre spese di viaggio correlate alla Sperimentazione. In caso di conflitto tra il consenso informato e il presente Contratto, il consenso informato prevarrà e regolerà tutte le questioni relative al rimborso delle spese di viaggio del soggetto. Se l'importo supera quanto consentito in conformità all'Allegato A-1, è necessario il previo consenso per iscritto da parte del Promotore.	The CRO will reimburse Payee in accordance with Attachment A-1 for reasonable ground travel expenses and overnight stays/meals incurred by Trial subjects in connection with their participation in the Trial. Payee's invoice to CRO for such expenses must include receipts for items such as meals, mileage, tolls, parking and other Trial related travel expenses. In the event that there is a conflict between the Informed Consent Form and this Agreement, the Informed Consent Form shall govern and control in all matters relating to subject travel expenses reimbursement. If the amount exceeds what is allowed for in accordance with Attachment A-1, prior written approval from Sponsor is required.
I. <u>EVENTI AVVERSI GRAVI</u>: il Promotore accetta di pagare al Beneficiario i costi effettivi sostenuti per il trattamento e la	**I. <u>SERIOUS ADVERSE EVENTS</u>**: Sponsor agrees to pay Payee for actual costs incurred in the processing and reporting of

segnalazione di eventi avversi gravi (di seguito "**SAE**") che si verificano in relazione alla Sperimentazione, fino al limite definito nel Budget, per ogni evento SAE. I pagamenti saranno effettuati entro quarantacinque (45) giorni dal ricevimento di una fattura dettagliata non contestata, come stabilito nell'Allegato A-1.	serious adverse events (hereinafter "**SAEs**") that occur in connection with the Trial, up to the limit defined in the Budget per SAE event. Payments will be made within forty-five (45) days of receipt of an undisputed itemized invoice as defined in Attachment A-1.
J. **COSTI E SERVIZI ACCESSORI DEL CENTRO DI SPERIMENTAZIONE:** Il presente Allegato A intende comprendere tutti i costi e i servizi correlati alla Sperimentazione. Qualora l'Ente desiderasse essere rimborsato per i costi relativi al trattamento del soggetto partecipante alla Sperimentazione o per le spese non specificate nel Budget relativo al soggetto o nei costi fissi (di seguito "**Costi e Servizi Accessori**"), l'Ente dovrà ottenere il previo consenso per iscritto da parte del Promotore. Esempi di Costi e Servizi Accessori includono, a titolo esemplificativo e non esaustivo, le forniture relative alla Sperimentazione e i materiali di trasporto relativi ai campioni biologici.	J. **ANCILLARY TRAIL SITE COSTS AND SERVICES:** This Annex A is intended to include all costs and services related to the Trial. In the event that the Institution wishes to be reimbursed for costs relating to Trial subject treatment or expenses that are not specified in the per subject Budget or fixed costs (hereinafter "**Ancillary Costs and Services**"), the Institution must obtain prior written approval from Sponsor. Examples of Ancillary Costs and Services include, but are not limited to, Trial-related supplies, and shipping materials related to biological samples.

Se l'Ente sostiene tali Costi o Servizi prima di ricevere l'approvazione del Promotore, il Promotore non sarà obbligato a corrispondere tali Costi o Servizi.	In the event the Institution incur such Costs or Services prior to receipt of Sponsor's approval, Sponsor will not be required to pay for such Costs or Services.
Se i Costi o Servizi Accessori sono stati approvati dal Promotore, l'Ente fatturerà al Promotore i Costi e/o i Servizi approvati senza maggiorazioni, quando vengono sostenuti. Il Promotore rimborserà l'Ente fino a un massimo di Euro 644,00 (seicentoquarantaquattro/00) dopo la ricezione della ragionevole documentazione relativa ai Costi o Servizi Accessori approvati. L'Ente deve ottenere il consenso per iscritto del Promotore prima di superare tale importo.	If Ancillary Costs or Services have been approved by Sponsor, Institution will invoice Sponsor for the approved Costs and/or Services without mark-up as they are incurred. Sponsor will reimburse the Institution up to a maximum of Euro 644.00 (six hundred and forty-four/00) after receiving reasonable documentation regarding the approved Ancillary Costs or Services. Institution must obtain written approval from Sponsor before exceeding this amount.
I pagamenti per i Costi o Servizi Accessori saranno effettuati entro quarantacinque (45) giorni dal ricevimento di una fattura dettagliata.	Payments for Ancillary Costs or Services will be made within forty-five (45) days of receipt of an itemized invoice.
K. <u>VISITE NON PROGRAMMATE</u>: le visite non programmate che si verificano dopo la randomizzazione e non nella stessa data di una visita di Sperimentazione regolarmente	**K. <u>UNSCHEDULED VISITS</u>:** Unscheduled visits that occur after randomization and not on the same date as a regularly scheduled Trial visit will be paid per procedure based

programmata saranno pagate per procedura in base alle singole procedure elencate nell'Allegato A-1 del budget. Il Promotore tramite CRO pagherà l'Ente entro 30 (trenta) giorni dal ricevimento di una fattura dettagliata indiscussa con la documentazione giustificativa della/e procedura/e eseguita/e.	on the individual procedures listed in Attachment A-1 of the budget. Sponsor through CRO will pay Institution within 30 (thirty) days of receipt of an undisputed itemized invoice with supporting documentation of procedure(s) performed.
L. <u>ALTRI COSTI:</u> Per qualsiasi altro costo, la CRO pagherà il Beneficiario entro quarantacinque (45) giorni dal ricevimento di una fattura dettagliata non contestata e come stabilito nell'Allegato A-1.	**L. <u>OTHER COSTS:</u>** For any other costs, the CRO will pay Payee within forty-five (45) days of receipt of an undisputed itemized invoice and as identified in Attachment A-1.
M. <u>FATTURE</u>:	**M. <u>INVOICES</u>**:
Le fatture dovranno essere intestate a:	Invoices should be made out to:
Regeneron Pharmaceuticals, Inc.	Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road	777 Old Saw Mill River Road
Tarrytown, NY 10591 Stati Uniti d'America	Tarrytown, NY 10591 USA
Alla cortese attenzione di: Accounts Payable	Attention: Accounts Payable
E inviate elettronicamente a:	AND sent electronically to:
InvestigatorPayments@iconplc.com	InvestigatorPayments@iconplc.com

Indicare quanto segue sulla riga dell'oggetto:	Please indicate following on the Subject line:
• Regeneron, n. di Protocollo Regeneron, nome dello Sperimentatore Principale	• Regeneron, Regeneron Protocol #, Principal Investigator name
Il pagamento delle fatture sarà effettuato entro quarantacinque (45) giorni dal ricevimento di una fattura originale completa recante le seguenti informazioni:	Payment for invoices will be made within forty-five (45) days of receipt of an original, complete invoice which includes the following information:
• Nome dell'Ente	• Institution name
• Nome dello Sperimentatore Principale	• Principal Investigator name
• Indirizzo postale	• Mailing address
• Numero di Protocollo	• Protocol number
• Numero del progetto: 0456/0556	• Project number: 0456/0556
• Partita IVA, se applicabile	• VAT Number, if applicable
• Numero di identificazione del Centro di Sperimentazione 380-228	• Trial Site identification number 380-228
• Numero e data della fattura	• Invoice number and date
• Periodo per il quale la fattura viene inviata	• Period for which the invoice is submitted
• Data e descrizione dei servizi forniti, comprese le visite dei pazienti interessate	• Date and description of services provided, including patient visits covered

• Adeguata documentazione di supporto (ad es. fatture, ricevute di terzi).	• Appropriate supporting documentation (i.e. third-party invoices, receipts).
Le fatture che non rechino alcune delle informazioni di cui sopra potrebbero dar luogo a pagamenti tardivi.	Invoices not including any of the designated information above, may result in delayed payments.
Fatture finali: Il Beneficiario deve fornire la fattura finale al Promotore e alla CRO entro sessanta (60) giorni dalla chiusura del Centro di Sperimentazione. Il Promotore non è responsabile del pagamento delle fatture inviate dopo tale periodo.	Final Invoices: Payee must provide the final invoice to Sponsor and CRO within sixty (60) days of Trial Site closure. Sponsor is not liable for payment of invoices sent after such time.
Il Beneficiario avrà trenta (30) giorni dal ricevimento del pagamento finale previsto dal presente Contratto per individuare discrepanze e risolvere dispute relative ai pagamenti.	Payee will have thirty (30) days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes.
N. <u>VIOLAZIONI DEL PROTOCOLLO</u>: Il Promotore si riserva il pieno diritto di negare il pagamento o la compensazione di somme dovute ai sensi del presente documento, per un pagamento precedentemente maturato per un soggetto partecipante alla Sperimentazione, nei casi in cui si sia verificata una violazione del Protocollo.	**N. <u>PROTOCOL VIOLATIONS</u>:** Sponsor retains the absolute right to deny payment or offset against sums due hereunder for a payment previously due for a Trial subject when a Protocol violation has occurred.

O. INFORMAZIONI DEL BENEFICIARIO: Il Beneficiario specificato nella tabella sottostante è legalmente idoneo e in grado di ricevere un compenso relativo alla sua prestazione ai sensi del presente Contratto. Se vengono modificati dettagli di fatturazione, un modulo dettagli Beneficiario deve essere inviato a InvestigatorPayments@iconplc.com. Nessun pagamento sarà effettuato al Beneficiario fino al completamento di quanto segue: (1) sottoscrizione del presente Contratto, (2) presentazione di tutti i documenti normativi alla CRO, (3) approvazione del Comitato Etico competente e (4) ricezione da parte della CRO del modulo dettagli Beneficiario compilato e firmato.	**O. PAYEE INFORMATION:** The Payee detailed in the table below is legally eligible and capable to receive compensation related to its performance under this Agreement. If any invoice detail is changed, a Beneficiary detail form shall be sent to InvestigatorPayments@iconplc.com. No payments will be made to the Payee until the following are completed: (1) execution of this Agreement, (2) submission of all regulatory documents to CRO, (3) competent Ethics Committee approval and (4) CRO receipt of the completed and signed Beneficiary detail form.
Tutti i pagamenti saranno effettuati a favore del Beneficiario indicato nella tabella sottostante.	All payments will be made to the Payee listed in the table below.

PAYEE INFORMATION	
Payable To	AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO PAOLO GIACCONE
Payee Mailing Address	Via Del Vespro 129 Palermo
Attention	/

Phone	091/6555535
Email	rosaria.mosca@policlinico.pa.it
Bank Name	Banca Nazionale del Lavoro S.p.A
Bank Branch Name	/
Bank Branch Address	Sede di via Roma n. 297 Palermo/Branch in Via Roma no. 297, Palermo
Bank ABA Routing Number	IT86P0100504600000000218030 SIC
Bank Account Name	/
Bank Account Number	C/C 218030
Swift Code (Optional)	BNLIITRR
NPI	CIN: P
Company Email Contact for Credit Remittance Advice	CAB:04600 ABI: 01005

ALLEGATO A-1 – BUDGET DETTAGLIATO | ANNEX A-1 – DETAILED BUDGET

Part 1A, Part 1B Regimen I, Part 2 Arm B

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Part 2: Only applicable if Regimen 1 is chosen)	C3D15 (Part 2: Only applicable if Regimen 1 is chosen)	C4D1
Informed consent	1	✔ ☐	48	1													
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290	1													
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42	1													
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200		1					1				1			1
Vital signs and assessment of B symptoms when required per protocol	104	✔ ☐	36			9	9	9	9	8	9	9	2	1	2	2	1
Eastern Cooperative Oncology Group (ECOG) Performance Status	34	✔ ☐	21	1	1	1		1		1				1			1

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Part 2: Only applicable if Regimen 1 is chosen)	C3D15 (Part 2: Only applicable if Regimen 1 is chosen)	C4D1
Adverse events	36	✔ ☐	26	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Concomitant medications/procedures	36	✔ ☐	23	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Neurological and mental status examination	1	✔ ☐	90			1											
12-lead ECG	2	✔ ☐	65	1													
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	30	✔ ☐	104			1	1	1	1	1	1	1	1	1	1	1	1
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79			3	3	3	3	3	3	3					
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104		1					1				1			1
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104		1					1				1			1
Prednisone/Prednisolone 100mg PO	6	✔ ☐			1					1				1			1
Hematology	32	✔ ☐	29	1	1	1				1				1			1
Blood chemistry	32	✔ ☐	66	1	1	1				1				1			1
Urinalysis	1	✔ ☐	11	1													
International Normalized Ratio	2	✔ ☐	21	1													

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Part 2: Only applicable if Regimen 1 is chosen)	C3D15 (Part 2: Only applicable if Regimen 1 is chosen)	C4D1
(INR)																	
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19	1													
Serum immunoglobulins (IgG)	23	✔ ☐	88	1													
HIV antibody	1	✔ ☐	40	1													
Hepatitis B core antibody	1	✔ ☐	38	1													
Hepatitis C antibody	1	✔ ☐	55	1													
CMV PCR	2	✔ ☐	64	1													
Collection of samples, PK and ADA	43	✔ ☐	29			2	2	2	2	2	2	2		2			2
Lab handling and/or shipping of specimen(s), PK and ADA	24	✔ ☐	27			1	1	1	1	1	1	1		1			1
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	25	✔ ☐	29		1	2	INV for Part 1	2	INV for Part 1	2	INV for Part 1	2		1			
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	21	✔ ☐	27		1	1	INV for Part 1	1	INV for Part 1	1	INV for Part 1	1		1			
Telephone evaluation	8	✔ ☐	52														

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Part 2: Only applicable if Regimen 1 is chosen)	C3D15 (Part 2: Only applicable if Regimen 1 is chosen)	C4D1
Patient Reported Outcome Assessments	17	✔ ☐	19		1					1							1
Beta-2 microglobulin	1	✔ ☐	49	1													
Procedures Sub Total				**995**	**648**	**1.090**	**799**	**905**	**799**	**1.391**	**799**	**884**	**225**	**854**	**225**	**225**	**817**

Procedure	Qty	OH	Budget	C4D8 (Part 2: Only applicable if Regimen 1 is chosen)	C4D15 (Part 2: Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Part 2: Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Part 2: Only applicable if Regimen 1 is chosen)	M1	M2	M3	M4	M5	M6	M7
Informed consent	1	✔ ☐	48													
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290													
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42													
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200			1		1		1	1	1	1	1	1	1
Vital signs and assessment of B symptoms when required per protocol	104	✔ ☐	36	2	2	1	2	1	2	2	2	2	2	2	2	2
Eastern Cooperative Oncology Group (ECOG) Performance Status	34	✔ ☐	21			1		1	1	1	1	1	1	1	1	1
Adverse events	36	✔ ☐	26	1	1	1	1	1	1	1	1	1	1	1	1	1
Concomitant medications/procedures	36	✔ ☐	23	1	1	1	1	1	1	1	1	1	1	1	1	1
Neurological and mental status examination	1	✔ ☐	90													
12-lead ECG	2	✔ ☐	65			1										
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	30	✔ ☐	104	1	1	1	1	1	1	1	1	1	1	1	1	1
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79													
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104			1		1								
Intravenous (IV) infusion for	6	✔ ☐	104			1		1								

Procedure	Qty	OH	Budget	C4D8 (Part 2: Only applicable if Regimen 1 is chosen)	C4D15 (Part 2: Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Part 2: Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Part 2: Only applicable if Regimen 1 is chosen)	M1	M2	M3	M4	M5	M6	M7
Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour																
Prednisone/Prednisolone 100mg PO	6	✔ ☐				1		1								
Hematology	32	✔ ☐	29			1		1		1	1	1	1	1	1	1
Blood chemistry	32	✔ ☐	66			1		1		1	1	1	1	1	1	1
Urinalysis	1	✔ ☐	11													
International Normalized Ratio (INR)	2	✔ ☐	21			1										
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19			1										
Serum immunoglobulins (IgG)	23	✔ ☐	88			1				1	1	1	1	1	1	1
HIV antibody	1	✔ ☐	40													
Hepatitis B core antibody	1	✔ ☐	38													
Hepatitis C antibody	1	✔ ☐	55													
CMV PCR	2	✔ ☐	64			1										
Collection of samples, PK and ADA	43	✔ ☐	29			2	2	2	2	2	2	2			2	
Lab handling and/or shipping of specimen(s), PK and ADA	24	✔ ☐	27			1	1	1	1	1	1	1			1	
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	25	✔ ☐	29					1		1	1	1				
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	21	✔ ☐	27					1		1	1	1				
Telephone evaluation	8	✔ ☐	52													
Patient Reported Outcome Assessments	17	✔ ☐	19					1					1			
Beta-2 microglobulin	1	✔ ☐	49													

Procedure	Qty	OH	Budget	C4D8 (Part 2: Only applicable if Regimen 1 is chosen)	C4D15 (Part 2: Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Part 2: Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Part 2: Only applicable if Regimen 1 is chosen)	M1	M2	M3	M4	M5	M6	M7
Procedures Sub Total				**225**	**225**	**1.055**	**310**	**873**	**331**	**770**	**770**	**770**	**648**	**629**	**714**	**629**

Procedure	Qty	OH	Budget	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4
Informed consent	1	✔ ☐	48													
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290													
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42													
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200	1	1	1	1	1	1	1	1	1	1	1	1	1
Vital signs and assessment of B symptoms when required per protocol	104	✔ ☐	36	2	2	2	2	2								
Eastern Cooperative Oncology Group (ECOG) Performance Status	34	✔ ☐	21	1	1	1	1	1	1	1	1	1	1	1	1	1
Adverse events	36	✔ ☐	26	1	1	1	1	1	1	1	1	1				
Concomitant medications/procedures	36	✔ ☐	23	1	1	1	1	1	1	1	1	1				
Neurological and mental status examination	1	✔ ☐	90													
12-lead ECG	2	✔ ☐	65													
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	30	✔ ☐	104	1	1	1	1	1								
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79													
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104													
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104													
Prednisone/Prednisolone 100mg PO	6	✔ ☐														
Hematology	32	✔ ☐	29	1	1	1	1	1	1	1	1	1	1	1	1	1
Blood chemistry	32	✔ ☐	66	1	1	1	1	1	1	1	1	1	1	1	1	1

Procedure	Qty	OH	Budget	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4
Urinalysis	1	✔ ☐	11													
International Normalized Ratio (INR)	2	✔ ☐	21													
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19													
Serum immunoglobulins (IgG)	23	✔ ☐	88	1	1	1	1	1				1	1	1	1	1
HIV antibody	1	✔ ☐	40													
Hepatitis B core antibody	1	✔ ☐	38													
Hepatitis C antibody	1	✔ ☐	55													
CMV PCR	2	✔ ☐	64													
Collection of samples, PK and ADA	43	✔ ☐	29		2			2	1	1	1	1		1		
Lab handling and/or shipping of specimen(s), PK and ADA	24	✔ ☐	27		1			1	1	1	1	1		1		
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	25	✔ ☐	29		1			1	1	1		1		1	1	1
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	21	✔ ☐	27		1			1	1	1		1		1	1	1
Telephone evaluation	8	✔ ☐	52													
Patient Reported Outcome Assessments	17	✔ ☐	19	1				1	1			1	1	1	1	1
Beta-2 microglobulin	1	✔ ☐	49													
Procedures Sub Total				**648**	**770**	**629**	**629**	**789**	**496**	**477**	**421**	**584**	**423**	**535**	**479**	**479**

Procedure	Qty	OH	Budget	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Informed consent	1	✔ ☐	48												
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290												
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42												
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200	1	1	1	1								
Vital signs and assessment of B symptoms when required per protocol	104	✔ ☐	36												
Eastern Cooperative Oncology Group (ECOG) Performance Status	34	✔ ☐	21	1	1	1	1								
Adverse events	36	✔ ☐	26												
Concomitant medications/procedures	36	✔ ☐	23												
Neurological and mental status examination	1	✔ ☐	90												
12-lead ECG	2	✔ ☐	65												
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	30	✔ ☐	104												
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79												
Intravenous (IV) infusion for Cyclophosphamide 750	6	✔ ☐	104												

Procedure	Qty	OH	Budget	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
mg/m2 IV up to 1 hour															
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104												
Prednisone/Prednisolone 100mg PO	6	✔ ☐													
Hematology	32	✔ ☐	29	1	1	1	1								
Blood chemistry	32	✔ ☐	66	1	1	1	1								
Urinalysis	1	✔ ☐	11												
International Normalized Ratio (INR)	2	✔ ☐	21												
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19												
Serum immunoglobulins (IgG)	23	✔ ☐	88	1	1	1	1								
HIV antibody	1	✔ ☐	40												
Hepatitis B core antibody	1	✔ ☐	38												
Hepatitis C antibody	1	✔ ☐	55												
CMV PCR	2	✔ ☐	64												
Collection of samples, PK and ADA	43	✔ ☐	29												
Lab handling and/or shipping of specimen(s), PK and ADA	24	✔ ☐	27												
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	25	✔ ☐	29	1	1		1								
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping,	21	✔ ☐	27	1	1		1								

Procedure	Qty	OH	Budget	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Cytokines, and/or ctDNA as required per protocol															
Telephone evaluation	8	✔ ☐	52					1	1	1	1	1	1	1	1
Patient Reported Outcome Assessments	17	✔ ☐	19	1	1	1	1								
Beta-2 microglobulin	1	✔ ☐	49												
Procedures Sub Total				**479**	**479**	**423**	**479**	**52**	**52**	**52**	**52**	**52**	**52**	**52**	**52**

Non Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Part 2: Only applicable if Regimen 1 is chosen)	C3D15 (Part 2: Only applicable if Regimen 1 is chosen)	C4D1
Coordination cost Physician	47	✔ ☐	104	2	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	47	✔ ☐	41	2	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	104	✔ ☐	42		2	8	8	8	8	8	8	8	2	2	2	2	2
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	42	✔ ☐	77		2	1	1	1	1	3	1	1	1	3	1	1	3
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36		1					1				1			1
Coordination cost data entry	45	✔ ☐	56	2	1	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**402**	**475**	**614**	**614**	**614**	**614**	**804**	**614**	**614**	**362**	**552**	**362**	**362**	**552**

Non Procedure	Qty	OH	Budget	C4D8 (Part 2: Only applicable if Regimen 1 is chosen)	C4D15 (Part 2: Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Part 2: Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Part 2: Only applicable if Regimen 1 is chosen)	M1	M2	M3	M4	M5	M6	M7
Coordination cost Physician	47	✔ ☐	104	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	47	✔ ☐	41	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	104	✔ ☐	42	2	2	2	2	2	2	2	2	2	2	2	2	2
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	42	✔ ☐	77	1	1	3	1	3	1	1	1	1	1	1	1	1
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36			1		1								
Coordination cost data entry	45	✔ ☐	56	1	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**362**	**362**	**552**	**362**	**552**	**362**	**362**	**362**	**362**	**362**	**362**	**362**	**362**

Non Procedure	Qty	OH	Budget	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4
Coordination cost Physician	47	✔ ☐	104	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	47	✔ ☐	41	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	104	✔ ☐	42	2	2	2	2	2								
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	42	✔ ☐	77	1	1	1	1	1								
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36													
Coordination cost data entry	45	✔ ☐	56	1	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**362**	**362**	**362**	**362**	**362**	**201**	**201**	**201**	**201**	**201**	**201**	**201**	**201**

Non Procedure	Qty	OH	Budget	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Coordination cost Physician	47	✔ ☐	104	1	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Study Coordinator	47	✔ ☐	41	1	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Nurse	104	✔ ☐	42												
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	42	✔ ☐	77												
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36												
Coordination cost data entry	45	✔ ☐	56	1	1	1	1								
Non Procedures Sub Total				**201**	**201**	**201**	**201**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**

	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Part 2: Only applicable if Regimen 1 is chosen)	C3D15 (Part 2: Only applicable if Regimen 1 is chosen)	C4D1
Costs not charged with OH														
Costs charged with OH	1.397 €	1.123 €	1.704 €	1.413 €	1.519 €	1.413 €	2.195 €	1.413 €	1.498 €	587 €	1.406 €	587 €	587 €	1.369 €
Overhead at 0%														
Selected Cost per Visit	**1.397 €**	**1.123 €**	**1.704 €**	**1.413 €**	**1.519 €**	**1.413 €**	**2.195 €**	**1.413 €**	**1.498 €**	**587 €**	**1.406 €**	**587 €**	**587 €**	**1.369 €**

	C4D8 (Part 2: Only applicable if Regimen 1 is chosen)	C4D15 (Part 2: Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Part 2: Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Part 2: Only applicable if Regimen 1 is chosen)	M1	M2	M3	M4	M5	M6	M7
Costs not charged with OH													
Costs charged with OH	587 €	587 €	1.607 €	672 €	1.425 €	693 €	1.132 €	1.132 €	1.132 €	1.010 €	991 €	1.076 €	991 €
Overhead at 0%													
Selected Cost per Visit	**587 €**	**587 €**	**1.607 €**	**672 €**	**1.425 €**	**693 €**	**1.132 €**	**1.132 €**	**1.132 €**	**1.010 €**	**991 €**	**1.076 €**	**991 €**

	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4
Costs not charged with OH													
Costs charged with OH	1.010 €	1.132 €	991 €	991 €	1.151 €	697 €	678 €	622 €	785 €	624 €	736 €	680 €	680 €
Overhead at 0%													
Selected Cost per Visit	**1.010 €**	**1.132 €**	**991 €**	**991 €**	**1.151 €**	**697 €**	**678 €**	**622 €**	**785 €**	**624 €**	**736 €**	**680 €**	**680 €**

	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Costs not charged with OH												
Costs charged with OH	680 €	680 €	624 €	680 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €
Overhead at 0%												
Selected Cost per Visit	**680 €**	**680 €**	**624 €**	**680 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**

Total Cost per subject **45,393.00 €**

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Genomics informed consent (optional)	1	✔ ☐	19	19	19	For participation in the Genomics Sub-Study
Collection of samples, Blood collection-genomic DNA (optional)	1	✔ ☐	29	29	29	For participation in the Genomics Sub-Study
Lab handling and/or shipping of specimen(s); genomic DNA	1	✔ ☐	27	27	27	For participation in the Genomics Sub-Study
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	30	✔ ☐	79	79	2.370	As needed for additional Infusion time not provided in the Study Visit.
Intravenous (IV) infusion for tocilizumab	30	✔ ☐	79	79	2.370	Invoiced as needed for CRS management
Intravenous (IV) infusion for Doxorubicin 50 mg/m2 IV up to 1 hour	6	✔ ☐	104	104	624	As needed
Pharmacy Dispensing Fee-Complex	36	✔ ☐	50	50	1.800	To be invoiced for dispensation of Doxorubicin or rescue medication as needed
Pharmacy Dispensing Fee-Simple (i.e., tablets)	31	✔ ☐	36	36	1.116	To be invoiced for dispensation of premedications as needed
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	1	✔ ☐	200	200	200	To be invoiced as needed for Unscheduled timepoint

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Neurological and mental status examination	1	✔	90	90	90	To be invoiced as needed for Unscheduled timepoint
Vital signs and assessment of B symptoms when required per protocol	13	✔	36	36	468	Additional vital sign checks may be invoiced for longer IV Infusion times during step-up period. May also be invoiced as needed for Unscheduled Visit.
12-lead ECG	1	✔	65	65	65	If/as clinically indicated for Unscheduled timepoint
Re-consent	3	✔	44	44	132	As needed
Serum pregnancy test	1	✔	31	31	31	To be invoiced as needed per Protocol along with Unscheduled visits.
Urine pregnancy test	19	✔	22	22	418	To be invoiced as needed per Protocol and/or for Unscheduled visits.
Hematology	1	✔	29	29	29	To be invoiced as needed for Unscheduled timepoint
Blood chemistry	1	✔	66	66	66	To be invoiced as needed for Unscheduled timepoint

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Adverse events	1	✔	26	26	26	To be invoiced as needed for Unscheduled timepoint
Concomitant medications/procedures	1	✔	23	23	23	To be invoiced as needed for Unscheduled timepoint
Physician - Per Hour	1	✔	104	104	104	To be invoiced as needed for Unscheduled timepoint
Study Coordinator - Per Hour	1	✔	41	41	41	To be invoiced as needed for Unscheduled timepoint
Data Entry - Per Hour	1	✔	56	56	56	To be invoiced as needed for Unscheduled timepoint
Lactate dehydrogenase (LD) (LDH)	31	✔	14	14	434	To be invoiced as needed per Protocol and/ or for Unscheduled timepoint if not included in routine blood chemistry panel.
Collection of samples, PK and ADA	1	✔	29	29	29	To be invoiced as needed for Unscheduled timepoint
Lab handling and/or shipping of specimen(s), PK and ADA	1	✔	27	27	27	To be invoiced as needed for Unscheduled timepoint

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	8	✔	29	29	232	To be invoiced as needed for additional Part 1 timepoints and/or at Unscheduled timepoint as necessary
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	6	✔	27	27	162	To be invoiced as needed for additional Part 1 timepoints and/or at Unscheduled timepoint as necessary
Telephone evaluation	1	✔	52	52	52	If/as needed for Unscheduled Visit
Archived tumor tissue and/or bone marrow sample	1	✔	148	148	148	To be invoiced as needed per Protocol.
Fine needle aspiration biopsy, including CT guidance; first lesion	3	✔	1.328	1.328	3.984	To be invoiced as needed per Protocol.
Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	3	✔	403	403	1.209	To be invoiced as needed per Protocol.
Ultrasonic guidance for needle placement	3	✔	319	319	957	To be invoiced as needed per Protocol.
Tumor/lymph node biopsy	3	✔	1.010	1.010	3.030	To be invoiced as needed per Protocol.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Anesthesia for intraperitoneal procedures in upper abdomen including laparoscopy; not otherwise specified	3	✔ ☐	596	596	1.788	To be invoiced as needed per Protocol.
Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; not otherwise specified	3	✔ ☐	546	546	1.638	To be invoiced as needed per Protocol.
Anesthesia for bone marrow aspiration and/or biopsy, anterior or posterior iliac crest	3	✔ ☐	320	320	960	To be invoiced as needed per Protocol.
Bone marrow biopsy; by trocar or needle	3	✔ ☐	439	439	1.317	To be invoiced as needed per Protocol.
Bone marrow aspiration, smear	3	✔ ☐	392	392	1.176	To be invoiced as needed per Protocol.
Level IV - Surgical pathology, gross and microscopic examination: Includes examination and reporting:	3	✔ ☐	265	265	795	To be invoiced as needed per Protocol.
Biopsy; Staining and preparation of the slides including shipping and handling	3	✔ ☐	124	124	372	To be invoiced as needed per Protocol.
Physician: Pathology - Per Hour	3	✔ ☐	78	78	234	Invoice as needed, as required by Protocol. Purpose is for local Interpretation and report of slide and/or block.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
FDG/PET or PET	14	✔	2.619	2.619	36.666	Invoice as needed, as required by Protocol
Interpretation and Report; FDG/PET or PET	14	✔	227	227	3.178	Invoice as needed, as required by Protocol
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	14	✔	616	616	8.624	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	14	✔	118	118	1.652	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	14	✔	574	574	8.036	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	14	✔	114	114	1.596	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	14	✔	699	699	9.786	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	14	✔	135	135	1.890	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	14	✔	652	652	9.128	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	14	✔	130	130	1.820	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Computed tomography, abdomen and pelvis; with contrast material(s)	14	✔	1.136	1.136	15.904	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computed tomography, abdomen and pelvis; with contrast material(s)	14	✔	208	208	2.912	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	14	✔	786	786	11.004	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	14	✔	136	136	1.904	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	14	✔	671	671	9.394	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	14	✔	131	131	1.834	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	14	✔	626	626	8.764	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	14	✔	130	130	1.820	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Brain MRI with contrast	14	✔	1.162	1.162	16.268	Invoice as needed, as required by Protocol
Brain MRI with Contrast: Interpretation and Report	14	✔	206	206	2.884	Invoice as needed, as required by Protocol
Brain MRI without contrast	14	✔	1.084	1.084	15.176	Invoice as needed, as required by Protocol
Brain MRI without Contrast: Interpretation and Report	14	✔	183	183	2.562	Invoice as needed, as required by Protocol
Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton): For Interpretation and Report use code R1551.	14	✔	1.281	1.281	17.934	Invoice as needed, as required by Protocol
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	14	✔	196	196	2.744	Invoice as needed, as required by Protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
MRI, abdomen, abdominal (MRI); with contrast material(s)	14	✔ ☐	961	961	13.454	Invoice as needed, as required by Protocol
Interpretation and Report; MRI, abdomen, abdominal (MRI); with contrast material(s)	14	✔ ☐	197	197	2.758	Invoice as needed, as required by Protocol
MRI, pelvis, pelvic (MRI); with contrast material(s)	14	✔ ☐	950	950	13.300	Invoice as needed, as required by Protocol
Interpretation and Report; MRI, pelvis, pelvic (MRI); with contrast material(s)	14	✔ ☐	192	192	2.688	Invoice as needed, as required by Protocol
MRI, orbit, face and neck (MRI); with contrast material(s)	14	✔ ☐	1.089	1.089	15.246	Invoice as needed, as required by Protocol
Interpretation and Report; MRI, orbit, face (MRI); with contrast material(s)	14	✔ ☐	319	319	4.466	Invoice as needed, as required by Protocol
MUGA	1	✔ ☐	569	569	569	Invoice as needed, as required by Protocol
MUGA, Interpretation and Report	1	✔ ☐	114	114	114	Invoice as needed, as required by Protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
ECHO	1	✔	261	261	261	Invoice as needed, as required by Protocol
ECHO, Interpretation and Report	1	✔	113	113	113	Invoice as needed, as required by Protocol
Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy	14	✔	64	64	896	To be invoiced as needed when copies of diagnostic films are required
Nurse - Per Hour	19	✔	42	42	798	To be invoiced, as needed, for additional nurse time for inpatient Close Monitoring for C2D15 and C3D1. Up to 6 nurse hours may be invoiced at each of these visits if inpatient monitoring of CRS is required. See Footnotes in Protocol for further details.
Overnight Facility Charge-Per Night	10	✔	1.414	1.414	14.140	To be invoiced, as needed, for Close Monitoring at the discretion of the PI. See Footnote in Protocol for further details.Cannot be invoiced in addition to Hotel Stay per each occurrence. Invoiceable up to C3D1, can be invoiced as an USV if needed beyond C3D1.
Hotel; Hotel stay per 24 hours, meals and transportation to/from site	10	✔	233	233	2.330	Alternative for patients dismissed from clinic who still need to be within 20 minutes of clinic in the event of CRS. Cannot be invoiced in addition to Overnight Faciity Charge per each occurrence. Invoiceable up to C3D1, can be invoiced as an USV if needed beyond C3D1.
Patient Reimbursement, Expenses, Patient Travel - Per Visit	44		30	30	1.320	Reimbursable as incurred, with receipts. **Applicable only for sites not using ClinCierge.**

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Daily Facility Charge Complex - Per day	1	✔	507	507	507	To be invoiced as needed
CMV PCR	2	✔	64	64	128	As clinically indicated in addition to timepoints noted in Protocol
Gonadotropin; follicle stimulating hormone (FSH)	1	✔	46	46	46	Invoiceable if required at screening.
Infectious agent antigen detection; hepatitis B surface antigen (HBsAg)	1	✔	76	76	76	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C quantification; HCV RNA, quantification	1	✔	205	205	205	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification	1	✔	95	95	95	Invoiceable if required at screening.

Footnotes

1. Maximum quantity payable per site is the total quantity multiplied by the number of subjects actually enrolled.
2. The parties agree that they will discuss any units that exceed the cap in good faith, leveraging the EDC data. All agreed upon changes must be included in a contract amendment.
3. For time points where only Study Coordinator time is referenced - it is expected that the Study Coordinator will complete all needed data entry.
4. All safety labs are to be collected and analyzed locally.
5. PK and BioMarkers to be collected and shipped by site for central analysis.
6. For step-up period and subsequent dosing visits, vital sign timepoints are a combination of SOC and research paid. Please reference the respective protocol footnote for additional details.
7. Any items not covered in the site budget should be considered SOC.
8. Visits C3D8, C3D15, C4D8, C4D15, C5D8, and C6D15 will not occur in Part 2 Arm B if Regimen 2 is chosen for Part 2.

Part 1B Regimen II

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C4D1	C5D1	C6D1	M1	M2
Informed consent	1	✔ ☐	48	1															
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290	1															
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42	1															
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200		1					1				1	1	1	1	1	1
Vital signs and assessment of B symptoms when required per protocol	92	✔ ☐	36			9	9	9	9	8	9	9	2	1	1	1	1	2	2
Eastern Cooperative Oncology Group (ECOG) Performance Status	33	✔ ☐	21	1	1	1		1		1				1	1	1	1	1	1
Adverse events	30	✔ ☐	26	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Concomitant medications/procedures	30	✔ ☐	23	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Neurological and mental status examination	1	✔ ☐	90		1														
12-lead ECG	2	✔ ☐	65	1												1			

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C4D1	C5D1	C6D1	M1	M2
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	24	✔	104			1	1	1	1	1	1	1	1	1	1	1	1	1	1
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔	79			3	3	3	3	3	3	3							
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔	104		1					1				1	1	1	1		
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔	104		1					1				1	1	1	1		
Prednisone/Prednisolone 100mg PO	6	✔			1					1				1	1	1	1		
Hematology	32	✔	29	1	1	1				1				1	1	1	1	1	1
Blood chemistry	32	✔	66	1	1	1				1				1	1	1	1	1	1
Urinalysis	1	✔	11	1															
International Normalized Ratio (INR)	2	✔	21	1												1			
Thromboplastin time, partial (PTT) (aPTT)	2	✔	19	1												1			
Serum immunoglobulins (IgG)	23	✔	88	1												1		1	1
HIV antibody	1	✔	40	1															
Hepatitis B core antibody	1	✔	38	1															
Hepatitis C antibody	1	✔	55	1															
CMV PCR	2	✔	64	1												1			
Collection of samples, PK and ADA	39	✔	29			2	2	2	2	2	2	2		2	2	2	2	2	2
Lab handling and/or shipping of specimen(s), PK and ADA	22	✔	27			1	1	1	1	1	1	1		1	1	1	1	1	1

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C4D1	C5D1	C6D1	M1	M2
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	32	✔	29		2	2	2	2	2	2	2	2		1			1	1	1
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	24	✔	27		1	1	1	1	1	1	1	1		1			1	1	1
Telephone evaluation	8	✔	52																
Patient Reported Outcome Assessments	25	✔	19		1					1					1		1	1	1
Beta-2 microglobulin	1	✔	49	1															
Procedures Sub Total				**995**	**767**	**1.000**	**884**	**905**	**884**	**1.391**	**884**	**884**	**225**	**854**	**817**	**1.055**	**873**	**789**	**789**

Procedure	Qty	OH	Budget	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Informed consent	1	✔ ☐	48																	
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290																	
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42																	
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vital signs and assessment of B symptoms when required per protocol	92	✔ ☐	36	2	2	2	2	2	2	2	2	2	2							
Eastern Cooperative Oncology Group (ECOG) Performance Status	33	✔ ☐	21	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Adverse events	30	✔ ☐	26	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
Concomitant medications/procedures	30	✔ ☐	23	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
Neurological and mental status examination	1	✔ ☐	90																	
12-lead ECG	2	✔ ☐	65																	
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	24	✔ ☐	104	1	1	1	1	1	1	1	1	1	1							

Procedure	Qty	OH	Budget	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79																	
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104																	
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104																	
Prednisone/Prednisolone 100mg PO	6	✔ ☐																		
Hematology	32	✔ ☐	29	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Blood chemistry	32	✔ ☐	66	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Urinalysis	1	✔ ☐	11																	
International Normalized Ratio (INR)	2	✔ ☐	21																	
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19																	
Serum immunoglobulins (IgG)	23	✔ ☐	88	1	1	1	1	1	1	1	1	1	1				1	1	1	1
HIV antibody	1	✔ ☐	40																	
Hepatitis B core antibody	1	✔ ☐	38																	
Hepatitis C antibody	1	✔ ☐	55																	
CMV PCR	2	✔ ☐	64																	
Collection of samples, PK and ADA	39	✔ ☐	29	2			2			2			2	1	1	1	1		1	
Lab handling and/or shipping of specimen(s), PK and ADA	22	✔ ☐	27	1			1			1			1	1	1	1	1		1	

Procedure	Qty	OH	Budget	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	32	✔ ☐	29	1						1			1	1	1		1		1	1
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	24	✔ ☐	27	1						1			1	1	1		1		1	1
Telephone evaluation	8	✔ ☐	52																	
Patient Reported Outcome Assessments	25	✔ ☐	19	1	1	1	1	1	1	1	1	1	1				1	1	1	1
Beta-2 microglobulin	1	✔ ☐	49																	
Procedures Sub Total				**789**	**648**	**648**	**733**	**648**	**648**	**789**	**648**	**648**	**789**	**477**	**477**	**421**	**584**	**423**	**535**	**479**

Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Informed consent	1	✔ ☐	48													
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290													
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42													
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200	1	1	1	1	1								
Vital signs and assessment of B symptoms when required per protocol	92	✔ ☐	36													
Eastern Cooperative Oncology Group (ECOG) Performance Status	33	✔ ☐	21	1	1	1	1	1								
Adverse events	30	✔ ☐	26													
Concomitant medications/procedures	30	✔ ☐	23													
Neurological and mental status examination	1	✔ ☐	90													

Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
12-lead ECG	2	✔ ☐	65													
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	24	✔ ☐	104													
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79													
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104													
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104													
Prednisone/Prednisolone 100mg PO	6	✔ ☐														
Hematology	32	✔ ☐	29	1	1	1	1	1								
Blood chemistry	32	✔ ☐	66	1	1	1	1	1								
Urinalysis	1	✔ ☐	11													
International Normalized Ratio (INR)	2	✔ ☐	21													
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19													
Serum immunoglobulins (IgG)	23	✔ ☐	88	1	1	1	1	1								
HIV antibody	1	✔ ☐	40													
Hepatitis B core antibody	1	✔ ☐	38													
Hepatitis C antibody	1	✔ ☐	55													
CMV PCR	2	✔ ☐	64													

Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Collection of samples, PK and ADA	39	✔ ☐	29													
Lab handling and/or shipping of specimen(s), PK and ADA	22	✔ ☐	27													
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	32	✔ ☐	29	1	1	1		1								
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	24	✔ ☐	27	1	1	1		1								
Telephone evaluation	8	✔ ☐	52						1	1	1	1	1	1	1	1
Patient Reported Outcome Assessments	25	✔ ☐	19	1	1	1	1	1								
Beta-2 microglobulin	1	✔ ☐	49													
Procedures Sub Total				**479**	**479**	**479**	**423**	**479**	**52**	**52**	**52**	**52**	**52**	**52**	**52**	**52**

Non Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C4D1	C5D1	C6D1	M1	M2
Coordination cost Physician	41	✔ ☐	104	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	41	✔ ☐	41	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	92	✔ ☐	42		2	8	8	8	8	8	8	8	2	2	2	2	2	2	2
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	36	✔ ☐	77		2	1	1	1	1	3	1	1	1	3	3	3	3	1	1
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36		1					1				1	1	1	1		
Coordination cost data entry	39	✔ ☐	56	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**402**	**475**	**614**	**614**	**614**	**614**	**804**	**614**	**614**	**362**	**552**	**552**	**552**	**552**	**362**	**362**

Non Procedure	Qty	OH	Budget	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Coordination cost Physician	41	✔ ☐	104	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	41	✔ ☐	41	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	92	✔ ☐	42	2	2	2	2	2	2	2	2	2	2							
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	36	✔ ☐	77	1	1	1	1	1	1	1	1	1	1							
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36																	
Coordination cost data entry	39	✔ ☐	56	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**362**	**362**	**362**	**362**	**362**	**362**	**362**	**362**	**362**	**362**	**201**	**201**	**201**	**201**	**201**	**201**	**201**

Non Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Coordination cost Physician	41	✔ ☐	104	1	1	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Study Coordinator	41	✔ ☐	41	1	1	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Nurse	92	✔ ☐	42													
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	36	✔ ☐	77													
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36													
Coordination cost data entry	39	✔ ☐	56	1	1	1	1	1								
Non Procedures Sub Total				**201**	**201**	**201**	**201**	**201**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**

	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C4D1	C5D1	C6D1	M1	M2
Costs not charged with OH																
Costs charged with OH	1.397 €	1.242 €	1.540 €	1.426 €	1.466 €	1.426 €	2.123 €	1.426 €	1.426 €	587 €	1.425 €	1.369 €	1.626 €	1.425 €	1.151 €	1.151 €
Overhead at 0%																
Selected Cost per Visit	**1.397 €**	**1.242 €**	**1.540 €**	**1.426 €**	**1.466 €**	**1.426 €**	**2.123 €**	**1.426 €**	**1.426 €**	**587 €**	**1.425 €**	**1.369 €**	**1.626 €**	**1.425 €**	**1.151 €**	**1.151 €**

	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Costs not charged with OH																	
Costs charged with OH	1.151 €	1.010 €	1.010 €	1.095 €	1.010 €	1.010 €	1.151 €	1.010 €	1.010 €	1.151 €	678 €	678 €	622 €	785 €	624 €	736 €	680 €
Overhead at 0%																	
Selected Cost per Visit	**1.151 €**	**1.010 €**	**1.010 €**	**1.095 €**	**1.010 €**	**1.010 €**	**1.151 €**	**1.010 €**	**1.010 €**	**1.151 €**	**678 €**	**678 €**	**622 €**	**785 €**	**624 €**	**736 €**	**680 €**

	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Costs not charged with OH													
Costs charged with OH	680 €	680 €	680 €	624 €	680 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €
Overhead at 0%													
Selected Cost per Visit	**680 €**	**680 €**	**680 €**	**624 €**	**680 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**

Total Cost per subject **41,667.00 €**

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Genomics informed consent (optional)	1	✔ ☐	19	19	19	For participation in the Genomics Sub-Study
Collection of samples, Blood collection-genomic DNA (optional)	1	✔ ☐	29	29	29	For participation in the Genomics Sub-Study
Lab handling and/or shipping of specimen(s); genomic DNA	1	✔ ☐	27	27	27	For participation in the Genomics Sub-Study
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	30	✔ ☐	79	79	2.370	As needed for additional Infusion time not provided in the Study Visit.
Intravenous (IV) infusion for tocilizumab	30	✔ ☐	79	79	2.370	As needed for CRS management
Intravenous (IV) infusion for Doxorubicin 50 mg/m2 IV up to 1 hour	6	✔ ☐	104	104	624	Invoice as needed, as required by protocol
Pharmacy Dispensing Fee-Complex	36	✔ ☐	50	50	1.800	To be invoiced for dispensation of Doxorubicin or rescue medication as needed
Pharmacy Dispensing Fee-Simple (i.e., tablets)	31	✔ ☐	36	36	1.116	To be invoiced for dispensation of Doxorubicin as needed

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	1	✔	200	200	200	To be invoiced as needed for Unscheduled timepoint
Neurological and mental status examination	1	✔	90	90	90	To be invoiced as needed for Unscheduled timepoint
Vital signs and assessment of B symptoms when required per protocol	13	✔	36	36	468	Additional vital sign checks may be invoiced for longer IV Infusion times during step-up period. May also be invoiced as needed for Unscheduled Visit.
12-lead ECG	1	✔	65	65	65	If/as clinically indicated for Unscheduled timepoint
Re-consent	3	✔	44	44	132	As needed
Serum pregnancy test	1	✔	31	31	31	Invoice as needed, as required by protocol
Urine pregnancy test	19	✔	22	22	418	To be invoiced as needed per Protocol and/or for Unscheduled visits.
Hematology	1	✔	29	29	29	To be invoiced as needed for Unscheduled timepoint

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Blood chemistry	1	✔	66	66	66	To be invoiced as needed for Unscheduled timepoint
Adverse events	1	✔	26	26	26	To be invoiced as needed for Unscheduled timepoint
Concomitant medications/procedures	1	✔	23	23	23	To be invoiced as needed for Unscheduled timepoint
Physician - Per Hour	1	✔	104	104	104	To be invoiced as needed for Unscheduled timepoint
Study Coordinator - Per Hour	1	✔	41	41	41	To be invoiced as needed for Unscheduled timepoint
Data Entry - Per Hour	1	✔	56	56	56	To be invoiced as needed for Unscheduled timepoint
Lactate dehydrogenase (LD) (LDH)	31	✔	14	14	434	To be invoiced as needed per Protocol and/ or for Unscheduled timepoint if not included in routine blood chemistry panel.
Collection of samples, PK and ADA	1	✔	29	29	29	To be invoiced as needed for Unscheduled timepoint

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Lab handling and/or shipping of specimen(s), PK and ADA	1	✔	27	27	27	To be invoiced as needed for Unscheduled timepoint
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	7	✔	29	29	203	To be invoiced as needed for additional Part 1 timepoints and/or at Unscheduled timepoint as necessary
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	6	✔	27	27	162	To be invoiced as needed for additional Part 1 timepoints and/or at Unscheduled timepoint as necessary
Telephone evaluation	1	✔	52	52	52	If/as needed for Unscheduled Visit
Archived tumor tissue and/or bone marrow sample	1	✔	148	148	148	Invoice as needed, as required by protocol
Fine needle aspiration biopsy, including CT guidance; first lesion	3	✔	1.328	1.328	3.984	Invoice as needed, as required by protocol
Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	3	✔	403	403	1.209	Invoice as needed, as required by protocol
Ultrasonic guidance for needle placement	3	✔	319	319	957	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Tumor/lymph node biopsy	3	✔	1.010	1.010	3.030	Invoice as needed, as required by protocol
Anesthesia for intraperitoneal procedures in upper abdomen including laparoscopy; not otherwise specified	3	✔	596	596	1.788	Invoice as needed, as required by protocol
Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; not otherwise specified	3	✔	546	546	1.638	Invoice as needed, as required by protocol
Anesthesia for bone marrow aspiration and/or biopsy, anterior or posterior iliac crest	3	✔	320	320	960	Invoice as needed, as required by protocol
Bone marrow biopsy; by trocar or needle	3	✔	439	439	1.317	Invoice as needed, as required by protocol
Bone marrow aspiration, smear	3	✔	392	392	1.176	Invoice as needed, as required by protocol
Level IV - Surgical pathology, gross and microscopic examination: Includes examination and reporting:	3	✔	265	265	795	Invoice as needed, as required by protocol
Biopsy; Staining and preparation of the slides including shipping and handling	3	✔	124	124	372	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Physician: Pathology - Per Hour	3	✔	78	78	234	Purpose is for local Interpretation and report of slide and/or block.
FDG/PET or PET	14	✔	2.619	2.619	36.666	Invoice as needed, as required by protocol
Interpretation and Report; FDG/PET or PET	14	✔	227	227	3.178	Invoice as needed, as required by protocol
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	14	✔	616	616	8.624	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	14	✔	118	118	1.652	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	14	✔	574	574	8.036	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	14	✔	114	114	1.596	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	14	✔	699	699	9.786	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	14	✔	135	135	1.890	Invoice as needed, as required by protocol
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	14	✔	652	652	9.128	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	14	✔	130	130	1.820	Invoice as needed, as required by protocol
Computed tomography, abdomen and pelvis; with contrast material(s)	14	✔	1.136	1.136	15.904	Invoice as needed, as required by protocol
Interpretation and Report; Computed tomography, abdomen and pelvis; with contrast material(s)	14	✔	208	208	2.912	Invoice as needed, as required by protocol
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	14	✔	786	786	11.004	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	14	✔	136	136	1.904	Invoice as needed, as required by protocol
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	14	✔	671	671	9.394	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	14	✔	131	131	1.834	Invoice as needed, as required by protocol
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	14	✔	626	626	8.764	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	14	✔	130	130	1.820	Invoice as needed, as required by protocol
Brain MRI with contrast	14	✔	1.162	1.162	16.268	Invoice as needed, as required by protocol
Brain MRI with Contrast: Interpretation and Report	14	✔	206	206	2.884	Invoice as needed, as required by protocol
Brain MRI without contrast	14	✔	1.084	1.084	15.176	Invoice as needed, as required by protocol
Brain MRI without Contrast: Interpretation and Report	14	✔	183	183	2.562	Invoice as needed, as required by protocol
Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton): For Interpretation and Report use code R1551.	14	✔	1.281	1.281	17.934	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	14	✔	196	196	2.744	Invoice as needed, as required by protocol
MRI, abdomen, abdominal (MRI); with contrast material(s)	14	✔	961	961	13.454	Invoice as needed, as required by protocol
Interpretation and Report; MRI, abdomen, abdominal (MRI); with contrast material(s)	14	✔	197	197	2.758	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
MRI, pelvis, pelvic (MRI); with contrast material(s)	14	✔	950	950	13.300	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; MRI, pelvis, pelvic (MRI); with contrast material(s)	14	✔	192	192	2.688	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
MRI, orbit, face and neck (MRI); with contrast material(s)	14	✔	1.089	1.089	15.246	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; MRI, orbit, face (MRI); with contrast material(s)	14	✔	319	319	4.466	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
MUGA	1	✔	569	569	569	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
MUGA, Interpretation and Report	1	✔	114	114	114	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
ECHO	1	✔	261	261	261	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
ECHO, Interpretation and Report	1	✔	113	113	113	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy	14	✔	64	64	896	To be invoiced as needed when copies of diagnostic films are required
Nurse - Per Hour	3	✔	42	42	126	Invoiceable at C2D15 and C3D1 if additional hours are needed for close monitoring. Can be invoiced as an USV if needed beyond C3D1.
Overnight Facility Charge-Per Night	10	✔	1.414	1.414	14.140	To be invoiced, as needed, for Close Monitoring at the discretion of the PI. See Footnote 11 in Protocol for further details.Cannot be invoiced in addition to Hotel Stay per each occurrence. Invoiceable up to C3D1, can be invoiced as an USV if needed beyond C3D1.
Hotel; Hotel stay per 24 hours, meals and transportation to/from site	10	✔	233	233	2.330	Alternative for patients dismissed from clinic who still need to be within 20 minutes of clinic in the event of CRS. Cannot be invoiced in addition to Overnight Faciity Charge per each occurrence. Invoiceable up to C3D1, can be invoiced as an USV if needed beyond C3D1.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Patient Reimbursement, Expenses, Patient Travel - Per Visit	39	☐	30	30	1.170	Reimbursable as incurred, with receipts. **Applicable only for sites not using ClinCierge.**
Daily Facility Charge Complex - Per day	1	✔	507	507	507	To be invoiced as needed
CMV PCR	2	✔	64	64	128	As clinically indicated in addition to timepoints noted in Protocol
Gonadotropin; follicle stimulating hormone (FSH)	1	✔	46	46	46	Invoiceable if required at screening.
Infectious agent antigen detection; hepatitis B surface antigen (HBsAg)	1	✔	76	76	76	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C quantification; HCV RNA, quantification	1	✔	205	205	205	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification	1	✔	95	95	95	Invoiceable if required at screening.

Footnotes

1. Maximum quantity payable per site is the total quantity multiplied by the number of subjects actually enrolled.
2. The parties agree that they will discuss any units that exceed the cap in good faith, leveraging the EDC data. All agreed upon changes must be included in a contract amendment.
3. For time points where only Study Coordinator time is referenced - it is expected that the Study Coordinator will complete all needed data entry.
4. All safety labs are to be collected and analyzed locally.
5. PK and BioMarkers to be collected and shipped by site for central analysis.
6. For step-up period, vital sign timepoints are a combination of SOC and research paid. Please reference the respective protocol footnote for additional details.
7. Any items not covered in the site budget should be considered SOC.

Part 2 Arm A

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Only applicable if Regimen 1 is chosen)	C3D15 (Only applicable if Regimen 1 is chosen)
Informed consent	1	✔ ☐	48	1											-	-
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290	1											-	-
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42	1											-	-
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	18	✔ ☐	200		1					1				1	-	-
Vital signs and assessment of B symptoms when required per protocol	80	✔ ☐	36			9	9	9	9	8	9	9	2	1	2	2
Eastern Cooperative Oncology Group (ECOG) Performance Status	22	✔ ☐	21	1	1	1		1		1				1	-	-
Adverse events	24	✔ ☐	26	1	1	1	1	1	1	1	1	1	1	1	1	1
Concomitant medications/procedures	24	✔ ☐	23	1	1	1	1	1	1	1	1	1	1	1	1	1
Neurological and mental status examination	1	✔ ☐	90			1									-	-
12-lead ECG	2	✔ ☐	65	1											-	-
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	18	✔ ☐	104			1	1	1	1	1	1	1	1	1	1	1
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79			3	3	3	3	3	3	3			-	-

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Only applicable if Regimen 1 is chosen)	C3D15 (Only applicable if Regimen 1 is chosen)
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104		1					1				1	-	-
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104		1					1				1	-	-
Prednisone / Prednisolone 100mg PO	6	✔ ☐			1					1				1	-	-
Hematology	20	✔ ☐	29	1	1	1				1				1	-	-
Blood chemistry	20	✔ ☐	66	1	1	1				1				1	-	-
Urinalysis	1	✔ ☐	11	1											-	-
International Normalized Ratio (INR)	2	✔ ☐	21	1											-	-
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19	1											-	-
Serum immunoglobulins (IgG)	11	✔ ☐	88	1											-	-
HIV antibody	1	✔ ☐	40	1											-	-
Hepatitis B core antibody	1	✔ ☐	38	1											–	–
Hepatitis C antibody	1	✔ ☐	55	1											-	-
CMV PCR	2	✔ ☐	64	1											-	-
Collection of samples, PK and ADA	31	✔ ☐	29			2	2	2	2	2	2	2		2		-
Lab handling and/or shipping of specimen(s), PK and ADA	18	✔ ☐	27			1	1	1	1	1	1	1		1		-
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	20	✔ ☐	29		1	2		2		2		2		1	-	-

Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Only applicable if Regimen 1 is chosen)	C3D15 (Only applicable if Regimen 1 is chosen)
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	16	✔ ☐	27		1	1		1		1		1		1	-	-
Telephone evaluation	8	✔ ☐	52												-	-
Patient Report Outcome Assessments	14	✔ ☐	19		1					1					-	-
Beta-2 microglobulin	1	✔ ☐	49	1											-	-
Procedures Sub Total				**995**	**648**	**1.090**	**799**	**905**	**799**	**1.391**	**799**	**884**	**225**	**854**	**225**	**225**

Procedure	Qty	OH	Budget	C4D1	C4D8 (Only applicable if Regimen 1 is chosen)	C4D15 (Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Only applicable if Regimen 1 is chosen)	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Informed consent	1	✔ ☐	48		-	-		-		-							
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290		-	-		-		-							
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42		-	-		-		-							
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	18	✔ ☐	200	1	-	-	1	-	1	-	1	1	1	1	1	1	1
Vital signs and assessment of B symptoms when required per protocol	80	✔ ☐	36	1	2	2	1	2	1	2							
Eastern Cooperative Oncology Group (ECOG) Performance Status	22	✔ ☐	21	1	-	-	1	-	1	1	1	1	1	1	1	1	1
Adverse events	24	✔ ☐	26	1	1	1	1	1	1	1	1	1	1	1			
Concomitant medications/procedures	24	✔ ☐	23	1	1	1	1	1	1	1	1	1	1	1			

Procedure	Qty	OH	Budget	C4D1	C4D8 (Only applicable if Regimen 1 is chosen)	C4D15 (Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Only applicable if Regimen 1 is chosen)	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Neurological and mental status examination	1	✔ ☐	90		-	-		-		-							
12-lead ECG	2	✔ ☐	65		-	-	1	-		-							
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	18	✔ ☐	104	1	1	1	1	1	1	1							
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79		-	-		-		-							
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104	1	-	-	1	-	1	-							
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104	1	-	-	1	-	1	-							
Prednisone / Prednisolone 100mg PO	6	✔ ☐		1	-	-	1	-	1	-							
Hematology	20	✔ ☐	29	1	-	-	1	-	1	-	1	1	1	1	1	1	1
Blood chemistry	20	✔ ☐	66	1	-	-	1	-	1	-	1	1	1	1	1	1	1
Urinalysis	1	✔ ☐	11		-	-		-		-							
International Normalized Ratio (INR)	2	✔ ☐	21		-	-	1	-		-							

Procedure	Qty	OH	Budget	C4D1	C4D8 (Only applicable if Regimen 1 is chosen)	C4D15 (Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Only applicable if Regimen 1 is chosen)	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19		-	-	1	-		-							
Serum immunoglobulins (IgG)	11	✔ ☐	88		-	-	1	-		-				1	1	1	1
HIV antibody	1	✔ ☐	40		-	-		-		-							
Hepatitis B core antibody	1	✔ ☐	38		–	–		–		–							
Hepatitis C antibody	1	✔ ☐	55		-	-		-		-							
CMV PCR	2	✔ ☐	64		-	-	1	-		-							
Collection of samples, PK and ADA	31	✔ ☐	29	2	-		2	2	2	2	1	1	1	1		1	
Lab handling and/or shipping of specimen(s), PK and ADA	18	✔ ☐	27	1	-		1	1	1	1	1	1	1	1		1	
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	20	✔ ☐	29		-	-		-	1	-	1	1		1		1	1
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	16	✔ ☐	27		-	-		-	1	-	1	1		1		1	1

Procedure	Qty	OH	Budget	C4D1	C4D8 (Only applicable if Regimen 1 is chosen)	C4D15 (Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Only applicable if Regimen 1 is chosen)	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Telephone evaluation	8	✔ ☐	52		-	-		-		-							
Patient Report Outcome Assessments	14	✔ ☐	19	1	-	-		-	1	-	1			1	1	1	1
Beta-2 microglobulin	1	✔ ☐	49		-	-		-		-							
Procedures Sub Total				**817**	**225**	**225**	**1.055**	**310**	**873**	**331**	**496**	**477**	**421**	**584**	**423**	**535**	**479**

Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Informed consent	1	✔ ☐	48													
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290													
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42													
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	18	✔ ☐	200	1	1	1	1	1								
Vital signs and assessment of B symptoms when required per protocol	80	✔ ☐	36													
Eastern Cooperative Oncology Group (ECOG) Performance Status	22	✔ ☐	21	1	1	1	1	1								
Adverse events	24	✔ ☐	26													
Concomitant medications/procedures	24	✔ ☐	23													
Neurological and mental status examination	1	✔ ☐	90													

Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
12-lead ECG	2	✔ ☐	65													
Intravenous (IV) infusion for Odronextamab therapy up to 1 hour	18	✔ ☐	104													
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	21	✔ ☐	79													
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104													
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104													
Prednisone / Prednisolone 100mg PO	6	✔ ☐														
Hematology	20	✔ ☐	29	1	1	1	1	1								
Blood chemistry	20	✔ ☐	66	1	1	1	1	1								
Urinalysis	1	✔ ☐	11													
International Normalized Ratio (INR)	2	✔ ☐	21													
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19													
Serum immunoglobulins (IgG)	11	✔ ☐	88	1	1	1	1	1								
HIV antibody	1	✔ ☐	40													
Hepatitis B core antibody	1	✔ ☐	38													

Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Hepatitis C antibody	1	✔ ☐	55													
CMV PCR	2	✔ ☐	64													
Collection of samples, PK and ADA	31	✔ ☐	29													
Lab handling and/or shipping of specimen(s), PK and ADA	18	✔ ☐	27													
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	20	✔ ☐	29	1	1	1		1								
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	16	✔ ☐	27	1	1	1		1								
Telephone evaluation	8	✔ ☐	52						1	1	1	1	1	1	1	1
Patient Report Outcome Assessments	14	✔ ☐	19	1	1	1	1	1								
Beta-2 microglobulin	1	✔ ☐	49													
Procedures Sub Total				**479**	**479**	**479**	**423**	**479**	**52**	**52**	**52**	**52**	**52**	**52**	**52**	**52**

Non Procedure	Qty	OH	Budget	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Only applicable if Regimen 1 is chosen)	C3D15 (Only applicable if Regimen 1 is chosen)
Coordination cost Physician	35	✔ ☐	104	2	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	35	✔ ☐	41	2	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	80	✔ ☐	42		2	8	8	8	8	8	8	8	2	2	2	2
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	30	✔ ☐	77		2	1	1	1	1	3	1	1	1	3	1	1
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36		1					1				1		
Coordination cost data entry	33	✔ ☐	56	2	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**402**	**475**	**614**	**614**	**614**	**614**	**804**	**614**	**614**	**362**	**552**	**362**	**362**

Non Procedure	Qty	OH	Budget	C4D1	C4D8 (Only applicable if Regimen 1 is chosen)	C4D15 (Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Only applicable if Regimen 1 is chosen)	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Coordination cost Physician	35	✔ ☐	104	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	35	✔ ☐	41	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	80	✔ ☐	42	2	2	2	2	2	2	2							
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	30	✔ ☐	77	3	1	1	3	1	3	1							
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36	1			1		1								
Coordination cost data entry	33	✔ ☐	56	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**552**	**362**	**362**	**552**	**362**	**552**	**362**	**201**	**201**	**201**	**201**	**201**	**201**	**201**

Non Procedure	Qty	OH	Budget	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Coordination cost Physician	35	✔ ☐	104	1	1	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Study Coordinator	35	✔ ☐	41	1	1	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Nurse	80	✔ ☐	42													
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	30	✔ ☐	77													
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36													
Coordination cost data entry	33	✔ ☐	56	1	1	1	1	1								
Non Procedures Sub Total				**201**	**201**	**201**	**201**	**201**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**

	SV	C1D1	C1D8	C1D9	C1D15	C1D16	C2D1	C2D2	C2D8	C2D15	C3D1	C3D8 (Only applicable if Regimen 1 is chosen)	C3D15 (Only applicable if Regimen 1 is chosen)
Costs not charged with OH													
Costs charged with OH	1.397	1.123	1.704	1.413	1.519	1.413	2.195	1.413	1.498	587	1.406	587	587
Overhead at 0%													
Selected Cost per Visit	**1.397 €**	**1.123 €**	**1.704 €**	**1.413 €**	**1.519 €**	**1.413 €**	**2.195 €**	**1.413 €**	**1.498 €**	**587 €**	**1.406 €**	**587 €**	**587 €**

	C4D1	C4D8 (Only applicable if Regimen 1 is chosen)	C4D15 (Only applicable if Regimen 1 is chosen)	C5D1	C5D8 (Only applicable if Regimen 1 is chosen)	C6D1	C6D15 (Only applicable if Regimen 1 is chosen)	EOT	30 Days Post EOT	60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3
Costs not charged with OH														
Costs charged with OH	1.369	587	587	1.607	672	1.425	693	697	678	622	785	624	736	680
Overhead at 0%														
Selected Cost per Visit	**1.369 €**	**587 €**	**587 €**	**1.607 €**	**672 €**	**1.425 €**	**693 €**	**697 €**	**678 €**	**622 €**	**785 €**	**624 €**	**736 €**	**680 €**

	Clinical F/U Q4	Clinical F/U Q5	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Costs not charged with OH													
Costs charged with OH	680	680	680	624	680	88,25	88,25	88,25	88,25	88,25	88,25	88,25	88,25
Overhead at 0%													
Selected Cost per Visit	**680 €**	**680 €**	**680 €**	**624 €**	**680 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**

Total Cost per subject **32,654.00 €**

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Genomics informed consent (optional)	1	✔ ☐	19	19	19	For participation in the Genomics Sub-Study
Collection of samples, PK and ADA	1	✔ ☐	29	29	29	To be invoiced as needed per Protocol along with Unscheduled visits.
Lab handling and/or shipping of specimen(s), PK and ADA	1	✔ ☐	27	27	27	To be invoiced as needed per Protocol along with Unscheduled visits.
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	1	✔ ☐	29	29	29	To be invoiced as needed per Protocol along with Unscheduled visits.
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	1	✔ ☐	27	27	27	To be invoiced as needed per Protocol along with Unscheduled visits.
Lab handling and/or shipping of specimen(s); genomic DNA	1	✔ ☐	27	27	27	For participation in the Genomics Sub-Study
Collection of samples, Blood collection-genomic DNA (optional)	1	✔ ☐	29	29	29	For participation in the Genomics Sub-Study
Re-consent	3	✔ ☐	44	44	132	As needed
Intravenous (IV) infusion for Odronextamab therapy for each additional hour	18	✔ ☐	79	79	1.422	As needed for additional Infusion time not provided in the Study Visit.
Intravenous (IV) infusion for tocilizumab therapy up to 1 hour	18	✔ ☐	79	79	1.422	As needed for CRS management
Intravenous (IV) infusion for Doxorubicin 50 mg/m2 IV up to 1 hour	6	✔ ☐	104	104	624	As needed
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	1	✔ ☐	200	200	200	To be invoiced as needed per Protocol along with Unscheduled visits.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Vital signs and assessment of B symptoms when required per protocol	18	✔ ☐	36	36	648	Additional vital sign checks may be invoiced for longer IV Infusion times during step-up period. May also be invoiced as needed for Unscheduled Visit.
Neurological and mental status examination	1	✔ ☐	90	90	90	To be invoiced as needed per Protocol along with Unscheduled visits.
Adverse events	1	✔ ☐	26	26	26	To be invoiced as needed per Protocol along with Unscheduled visits.
Concomitant medications/procedures	1	✔ ☐	23	23	23	To be invoiced as needed per Protocol along with Unscheduled visits.
Hematology	1	✔ ☐	29	29	29	To be invoiced as needed per Protocol along with Unscheduled visits.
Blood chemistry	1	✔ ☐	66	66	66	To be invoiced as needed per Protocol along with Unscheduled visits.
Pharmacy Dispensing Fee-Complex	24	✔ ☐	50	50	1.200	To be invoiced for dispensation of Doxorubicin as needed
Pharmacy Dispensing Fee-Simple (i.e., tablets)	18	✔ ☐	36	36	648	To be invoiced for dispensation of premedications as needed
Physician - Per Hour	1	✔ ☐	104	104	104	To be invoiced as needed per Protocol along with Unscheduled visits.
Study Coordinator - Per Hour	1	✔ ☐	41	41	41	To be invoiced as needed per Protocol along with Unscheduled visits.
Data Entry - Per Hour	1	✔ ☐	56	56	56	To be invoiced as needed per Protocol along with Unscheduled visits.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
12-lead ECG	1	✔	65	65	65	If/as clinically indicated
ECHO	1	✔	261	261	261	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
ECHO, Interpretation and Report	1	✔	113	113	113	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
MUGA	1	✔	569	569	569	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
MUGA, Interpretation and Report	1	✔	114	114	114	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy	9	✔	64	64	576	To be invoiced as needed per Protocol.
Lactate dehydrogenase (LD) (LDH)	19	✔	14	14	266	To be invoiced as needed per Protocol along with Unscheduled visits if not included in routine blood chemistry panel
Serum pregnancy test	1	✔	31	31	31	To be invoiced as needed per Protocol along with Unscheduled visits.
Urine pregnancy test	8	✔	22	22	176	To be invoiced as needed per Protocol along with Unscheduled visits.
Fine needle aspiration biopsy, including CT guidance; first lesion	3	✔	1.328	1.328	3.984	Invoice as needed, as required by Protocol
Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	3	✔	403	403	1.209	Invoice as needed, as required by Protocol
Ultrasonic guidance for needle placement	3	✔	319	319	957	Invoice as needed, as required by Protocol
Tumor/lymph node biopsy	3	✔	1.010	1.010	3.030	Invoice as needed, as required by Protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Anesthesia for intraperitoneal procedures in upper abdomen including laparoscopy; not otherwise specified	3	✔	596	596	1.788	Invoice as needed, as required by Protocol
Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; not otherwise specified	3	✔	546	546	1.638	Invoice as needed, as required by Protocol
Anesthesia for bone marrow aspiration and/or biopsy, anterior or posterior iliac crest	3	✔	320	320	960	Invoice as needed, as required by Protocol
Bone marrow biopsy; by trocar or needle	3	✔	439	439	1.317	Invoice as needed, as required by Protocol
Bone marrow aspiration, smear	3	✔	392	392	1.176	Invoice as needed, as required by Protocol
Level IV - Surgical pathology, gross and microscopic examination: Includes examination and reporting:	3	✔	265	265	795	Invoice as needed, as required by Protocol
Biopsy; Staining and preparation of the slides including shipping and handling	3	✔	124	124	372	Invoice as needed, as required by Protocol
Coordination cost Physician: Pathology	3	✔	78	78	234	Invoice as needed, as required by Protocol. Purpose is for local Interpretation and report of slide and/or block.
Archived tumor tissue and/or bone marrow sample	1	✔	148	148	148	To be invoiced as needed per Protocol.
Telephone evaluation	1	✔	52	52	52	If/as needed for Unscheduled Visit
FDG/PET or PET	9	✔	2.619	2.619	23.571	Invoice as needed, as required by Protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Interpretation and Report; FDG/PET or PET	9	✔	227	227	2.043	Invoice as needed, as required by Protocol
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	9	✔	616	616	5.544	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	9	✔	118	118	1.062	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	9	✔	574	574	5.166	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	9	✔	114	114	1.026	Invoice as needed, as required by Protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	9	✔	699	699	6.291	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	9	✔	135	135	1.215	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	9	✔	652	652	5.868	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	9	✔	130	130	1.170	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Computed tomography, abdomen and pelvis; with contrast material(s)	9	✔	1.136	1.136	10.224	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Interpretation and Report; Computed tomography, abdomen and pelvis; with contrast material(s)	9	✔	208	208	1.872	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	9	✔	786	786	7.074	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	9	✔	136	136	1.224	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	9	✔	671	671	6.039	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	9	✔	131	131	1.179	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	9	✔	626	626	5.634	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	9	✔	130	130	1.170	Invoice as needed, as required by Protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Brain MRI with contrast	9	✔	1.162	1.162	10.458	Invoice as needed, as required by Protocol
Brain MRI with Contrast: Interpretation and Report	9	✔	206	206	1.854	Invoice as needed, as required by Protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Brain MRI without contrast	9	✔	1.084	1.084	9.756	Invoice as needed, as required by Protocol
Brain MRI without Contrast: Interpretation and Report	9	✔	183	183	1.647	Invoice as needed, as required by Protocol
Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton): For Interpretation and Report use code R1551.	9	✔	1.281	1.281	11.529	Invoice as needed, as required by Protocol
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	9	✔	196	196	1.764	Invoice as needed, as required by Protocol
MRI, abdomen, abdominal (MRI); with contrast material(s)	9	✔	961	961	8.649	Invoice as needed, as required by Protocol
Interpretation and Report; MRI, abdomen, abdominal (MRI); with contrast material(s)	9	✔	197	197	1.773	Invoice as needed, as required by Protocol
MRI, pelvis, pelvic (MRI); with contrast material(s)	9	✔	950	950	8.550	Invoice as needed, as required by Protocol
Interpretation and Report; MRI, pelvis, pelvic (MRI); with contrast material(s)	9	✔	192	192	1.728	Invoice as needed, as required by Protocol
MRI, orbit, face and neck (MRI); with contrast material(s)	9	✔	1.089	1.089	9.801	Invoice as needed, as required by Protocol
Interpretation and Report; MRI, orbit, face (MRI); with contrast material(s)	9	✔	319	319	2.871	Invoice as needed, as required by Protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Coordination cost Nurse	12	✔	42	42	504	To be invoiced, as needed, for additional nurse time for inpatient Close Monitoring for C2D15 and C3D1. Up to 6 nurse hours may be invoiced at each of these visits if inpatient monitoring of CRS is required. See Footnotes in Protocol for further details.
Overnight Facility Charge-Per Night	9	✔	1.414	1.414	12.726	To be invoiced, as needed, for Close Monitoring at the discretion of the PI. See Footnote in Protocol for further details.Cannot be invoiced in addition to Hotel Stay per each occurrence. Invoiceable up to C3D1, can be invoiced as an USV if needed beyond C3D1.
Hotel; Hotel stay per 24 hours, meals and transportation to/from site	9	✔	233	233	2.097	Alternative for patients dismissed from clinic who still need to be within 20 minutes of clinic in the event of CRS. Cannot be invoiced in addition to Overnight Faciity Charge per each occurrence. Invoiceable up to C3D1, can be invoiced as an USV if needed beyond C3D1.
Patient Reimbursement, Expenses, Patient Travel - Per Visit	32		30	30	960	Reimbursable as incurred, with receipts. Applicable only for sites not using ClinCierge.
Daily Facility Charge Complex - Per day	1	✔	586	586	586	To be invoiced as needed
CMV PCR	2	✔	64	64	128	As clinically indicated in addition to timepoints noted in Protocol
Gonadotropin; follicle stimulating hormone (FSH)	1	✔	46	46	46	Invoiceable if required at screening.
Infectious agent antigen detection; hepatitis B surface antigen (HBsAg)	1	✔	76	76	76	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C quantification; HCV RNA, quantification	1	✔	205	205	205	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification	1	✔	95	95	95	Invoiceable if required at screening.

Footnotes

1. Maximum quantity payable per site is the total quantity multiplied by the number of subjects actually enrolled.
2. The parties agree that they will discuss any units that exceed the cap in good faith, leveraging the EDC data. All agreed upon changes must be included in a contract amendment.
3. For time points where only Study Coordinator time is referenced - it is expected that the Study Coordinator will complete all needed data entry.
4. All safety labs are to be collected and analyzed locally.
5. PK and BioMarkers to be collected and shipped by site for central analysis.
6. For step-up period, vital sign timepoints are a combination of SOC and research paid. Please reference the respective protocol footnote for additional details.
7. Any items not covered in the site budget should be considered SOC.
8. Visits C3D8, C3D15, C4D8, C4D15, C5D8, and C6D15 will not occur if Regimen 2 is chosen after Part 1 analysis is completed.

Arm C (R-CHOP)

Procedure	Qty	OH	Budget	SV	C1D1	C2D1	C3D1	C4D1	C5D1	C6D1	M1	M2	M3	M4	M5	M6
Informed consent	1	✔ ☐	48	1												
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290	1												
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42	1												
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200		1	1	1	1	1	1	1	1	1	1	1	1
Vital signs and assessment of B symptoms when required per protocol	16	✔ ☐	36				1	1	1	1	1	1	1	1	1	1
Eastern Cooperative Oncology Group (ECOG) Performance Status	31	✔ ☐	21	1	1	1	1	1	1	1	1	1	1	1	1	1
Adverse events	23	✔ ☐	26	1	1	1	1	1	1	1	1	1	1	1	1	1
Concomitant medications/procedures	23	✔ ☐	23	1	1	1	1	1	1	1	1	1	1	1	1	1
12-lead ECG	2	✔ ☐	65	1					1							
Intravenous (IV) infusion for Rituximab therapy up to 1 hour	1	✔ ☐	104		1	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV	INV
Intravenous (IV) infusion for Rituximab therapy for each additional hour	1	✔ ☐	79		1											
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104		1	1	1	1	1	1						
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104		1	1	1	1	1	1						
Prednisone / Prednisolone 100mg PO	6	✔ ☐			1	1	1	1	1	1						
Hematology	31	✔ ☐	29	1	1	1	1	1	1	1	1	1	1	1	1	1
Blood chemistry	31	✔ ☐	66	1	1	1	1	1	1	1	1	1	1	1	1	1
Urinalysis	1	✔ ☐	11	1												

Procedure	Qty	OH	Budget	SV	C1D1	C2D1	C3D1	C4D1	C5D1	C6D1	M1	M2	M3	M4	M5	M6
International Normalized Ratio (INR)	2	✔ ☐	21	1					1							
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19	1					1							
Serum immunoglobulins (IgG)	23	✔ ☐	88	1					1		1	1	1	1	1	1
HIV antibody	1	✔ ☐	40	1												
Hepatitis B core antibody	1	✔ ☐	38	1												
Hepatitis C antibody	1	✔ ☐	55	1												
CMV PCR	2	✔ ☐	64	1					1							
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	14	✔ ☐	29		1		1			1	1	1	1			
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	14	✔ ☐	27		1		1			1	1	1	1			
Telephone evaluation	8	✔ ☐	52													
Patient Reported Outcome Assessments	25	✔ ☐	19		1	1		1		1	1	1	1	1	1	1
Beta-2 microglobulin	1	✔ ☐	49	1												
Procedures Sub Total				**995**	**831**	**592**	**665**	**628**	**866**	**684**	**564**	**564**	**564**	**508**	**508**	**508**

Procedure	Qty	OH	Budget	M7	M8	M9	M10	M11	M12	EOT	Clinical F/U 30 Days Post EOT	Clinical F/U 60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4	Clinical F/U Q5
Informed consent	1	✔ ☐	48															
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290															
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42															
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vital signs and assessment of B symptoms when required per protocol	16	✔ ☐	36	1	1	1	1	1	1									
Eastern Cooperative Oncology Group (ECOG) Performance Status	31	✔ ☐	21	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Adverse events	23	✔ ☐	26	1	1	1	1	1	1	1	1	1	1					
Concomitant medications/procedures	23	✔ ☐	23	1	1	1	1	1	1	1	1	1	1					
12-lead ECG	2	✔ ☐	65															
Intravenous (IV) infusion for Rituximab therapy up to 1 hour	1	✔ ☐	104	INV	INV	INV	INV	INV	INV									
Intravenous (IV) infusion for Rituximab therapy for each additional hour	1	✔ ☐	79															

Procedure	Qty	OH	Budget	M7	M8	M9	M10	M11	M12	EOT	Clinical F/U 30 Days Post EOT	Clinical F/U 60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4	Clinical F/U Q5
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104															
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104															
Prednisone / Prednisolone 100mg PO	6	✔ ☐																
Hematology	31	✔ ☐	29	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Blood chemistry	31	✔ ☐	66	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Urinalysis	1	✔ ☐	11															
International Normalized Ratio (INR)	2	✔ ☐	21															
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19															
Serum immunoglobulins (IgG)	23	✔ ☐	88	1	1	1	1	1	1				1	1	1	1	1	1
HIV antibody	1	✔ ☐	40															
Hepatitis B core antibody	1	✔ ☐	38															
Hepatitis C antibody	1	✔ ☐	55															
CMV PCR	2	✔ ☐	64															
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	14	✔ ☐	29			1			1	1	1		1		1		1	

Procedure	Qty	OH	Budget	M7	M8	M9	M10	M11	M12	EOT	Clinical F/U 30 Days Post EOT	Clinical F/U 60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4	Clinical F/U Q5
Telephone evaluation	8	✔ ☐	52															
Patient Reported Outcome Assessments	25	✔ ☐	19	1	1	1	1	1	1				1	1	1	1	1	1
Beta-2 microglobulin	1	✔ ☐	49															
Procedures Sub Total				**508**	**508**	**564**	**508**	**508**	**564**	**421**	**421**	**365**	**528**	**423**	**479**	**423**	**479**	**423**

Procedure	Qty	OH	Budget	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Informed consent	1	✔ ☐	48											
Initial examination: Includes a comprehensive medical/oncologic history, a comprehensive physical examination including vital signs, height, weight, and assessment for B symptoms	1	✔ ☐	290											
Inclusion/Exclusion criteria with Demographics	1	✔ ☐	42											
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	30	✔ ☐	200	1	1	1								
Vital signs and assessment of B symptoms when required per protocol	16	✔ ☐	36											
Eastern Cooperative Oncology Group (ECOG) Performance Status	31	✔ ☐	21	1	1	1								
Adverse events	23	✔ ☐	26											
Concomitant medications/procedures	23	✔ ☐	23											
12-lead ECG	2	✔ ☐	65											
Intravenous (IV) infusion for Rituximab therapy up to 1 hour	1	✔ ☐	104											
Intravenous (IV) infusion for Rituximab therapy for each additional hour	1	✔ ☐	79											
Intravenous (IV) infusion for Cyclophosphamide 750 mg/m2 IV up to 1 hour	6	✔ ☐	104											
Intravenous (IV) infusion for Vincristine 1.4 mg/m2 IV (max 2 mg) up to 1 hour	6	✔ ☐	104											

Procedure	Qty	OH	Budget	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Prednisone / Prednisolone 100mg PO	6	✔ ☐												
Hematology	31	✔ ☐	29	1	1	1								
Blood chemistry	31	✔ ☐	66	1	1	1								
Urinalysis	1	✔ ☐	11											
International Normalized Ratio (INR)	2	✔ ☐	21											
Thromboplastin time, partial (PTT) (aPTT)	2	✔ ☐	19											
Serum immunoglobulins (IgG)	23	✔ ☐	88	1	1	1								
HIV antibody	1	✔ ☐	40											
Hepatitis B core antibody	1	✔ ☐	38											
Hepatitis C antibody	1	✔ ☐	55											
CMV PCR	2	✔ ☐	64											
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	14	✔ ☐	29			1								
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	14	✔ ☐	27			1								
Telephone evaluation	8	✔ ☐	52				1	1	1	1	1	1	1	1
Patient Reported Outcome Assessments	25	✔ ☐	19	1	1	1								
Beta-2 microglobulin	1	✔ ☐	49											
Procedures Sub Total				**423**	**423**	**479**	**52**	**52**	**52**	**52**	**52**	**52**	**52**	**52**

Non Procedure	Qty	OH	Budget	SV	C1D1	C2D1	C3D1	C4D1	C5D1	C6D1	M1	M2	M3	M4	M5	M6
Coordination cost Physician	34	✔ ☐	104	2	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	34	✔ ☐	41	2	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	26	✔ ☐	42		4	2	2	2	2	2	1	1	1	1	1	1
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	30	✔ ☐	77		3	3	3	3	3	3	1	1	1	1	1	1
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36		1	1	1	1	1	1						
Coordination cost data entry	32	✔ ☐	56	2	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**402**	**636**	**552**	**552**	**552**	**552**	**552**	**320**	**320**	**320**	**320**	**320**	**320**

Non Procedure	Qty	OH	Budget	M7	M8	M9	M10	M11	M12	EOT	Clinical F/U 30 Days Post EOT	Clinical F/U 60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4	Clinical F/U Q5
Coordination cost Physician	34	✔ ☐	104	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Study Coordinator	34	✔ ☐	41	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Coordination cost Nurse	26	✔ ☐	42	1	1	1	1	1	1									
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	30	✔ ☐	77	1	1	1	1	1	1									
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36															
Coordination cost data entry	32	✔ ☐	56	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Non Procedures Sub Total				**320**	**320**	**320**	**320**	**320**	**320**	**201**	**201**	**201**	**201**	**201**	**201**	**201**	**201**	**201**

Non Procedure	Qty	OH	Budget	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Coordination cost Physician	34	✔ ☐	104	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Study Coordinator	34	✔ ☐	41	1	1	1	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Coordination cost Nurse	26	✔ ☐	42											
Pharmacy Dispensing Fee-Complex (Drug delivery to enrolled subject for infusion drugs + IWRS)	30	✔ ☐	77											
Pharmacy Dispensing Fee-Simple (i.e., tablets) (this fee covers all costs incurred by the site concerning premedication drugs)	6	✔ ☐	36											
Coordination cost data entry	32	✔ ☐	56	1	1	1								
Non Procedures Sub Total				**201**	**201**	**201**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**	**36,25**

	SV	C1D1	C2D1	C3D1	C4D1	C5D1	C6D1	M1	M2	M3	M4	M5	M6
Costs not charged with OH													
Costs charged with OH	1.397 €	1.467 €	1.144 €	1.217 €	1.180 €	1.418 €	1.236 €	884 €	884 €	884 €	828 €	828 €	828 €
Overhead at 0%													
Selected Cost per Visit	**1.397 €**	**1.467 €**	**1.144 €**	**1.217 €**	**1.180 €**	**1.418 €**	**1.236 €**	**884 €**	**884 €**	**884 €**	**828 €**	**828 €**	**828 €**

	M7	M8	M9	M10	M11	M12	EOT	Clinical F/U 30 Days Post EOT	Clinical F/U 60 Days Post EOT	Clinical F/U 90 Days Post Last Dose	Clinical F/U Q1	Clinical F/U Q2	Clinical F/U Q3	Clinical F/U Q4	Clinical F/U Q5
Costs not charged with OH															
Costs charged with OH	828 €	828 €	884 €	828 €	828 €	884 €	622 €	622 €	566 €	729 €	624 €	680 €	624 €	680 €	624 €
Overhead at 0%															
Selected Cost per Visit	**828 €**	**828 €**	**884 €**	**828 €**	**828 €**	**884 €**	**622 €**	**622 €**	**566 €**	**729 €**	**624 €**	**680 €**	**624 €**	**680 €**	**624 €**

	Clinical F/U Q6	Clinical F/U Q7	Clinical F/U Q8	Survival F/U Q1	Survival F/U Q2	Survival F/U Q3	Survival F/U Q4	Survival F/U Q5	Survival F/U Q6	Survival F/U Q7	Survival F/U Q8
Costs not charged with OH											
Costs charged with OH	624 €	624 €	680 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €	88,25 €
Overhead at 0%											
Selected Cost per Visit	**624 €**	**624 €**	**680 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**	**88,25 €**

Total Cost per subject **27,680.00 €**

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Genomics informed consent (optional)	1	✔ ☐	19	19	19	For participation in the Genomics Sub-Study
Collection of samples, Blood collection-genomic DNA (optional)	1	✔ ☐	29	29	29	For participation in the Genomics Sub-Study
Lab handling and/or shipping of specimen(s); genomic DNA	1	✔ ☐	27	27	27	For participation in the Genomics Sub-Study
Intravenous (IV) infusion for Rituximab therapy up to 1 hour	17	✔ ☐	104	104	1.768	All participants must receive at least 1 full dose of a rituximab product by IV infusion before receiving rituximab SC injection.
Intravenous (IV) infusion for Rituximab therapy for each additional hour	17	✔ ☐	79	79	1.343	As needed for additional Infusion time if exceeds 1 hour.
Rituximab administration (SC injection)	17	✔ ☐	43	43	731	All participants must receive at least 1 full dose of a rituximab product by IV infusion before receiving rituximab SC injection.
Intravenous (IV) infusion for Doxorubicin 50 mg/m2 IV up to 1 hour	6	✔ ☐	104	104	624	Invoice as needed, as required by protocol
Pharmacy Dispensing Fee-Complex	7	✔ ☐	50	50	350	To be invoiced for dispensation of Doxorubicin or rescue medication as needed
Intravenous (IV) infusion for tocilizumab	1	✔ ☐	104	104	104	As needed for CRS management
Pharmacy Dispensing Fee-Complex	1	✔ ☐	50	50	50	To be invoiced for dispensation of tocilizumab as needed

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Limited Physical and Lymphatic Exams: Includes vital signs, weight, and assessment for B symptoms as required per protocol	1	✔	200	200	200	To be invoiced as needed for Unscheduled timepoint
Vital signs	18	✔	36	36	648	Additional vital sign checks may be invoiced for longer IV Infusion times as needed. May also be invoiced as needed for Unscheduled Visit.
12-lead ECG	1	✔	65	65	65	If/as clinically indicated for Unscheduled timepoint
Re-consent	3	✔	44	44	132	As needed
Serum pregnancy test	1	✔	31	31	31	To be invoiced as needed per Protocol along with Unscheduled visits.
Urine pregnancy test	19	✔	22	22	418	To be invoiced as needed per Protocol and/or for Unscheduled visits.
Hematology	1	✔	29	29	29	To be invoiced as needed for Unscheduled timepoint
Blood chemistry	1	✔	66	66	66	To be invoiced as needed for Unscheduled timepoint
Adverse events	1	✔	26	26	26	To be invoiced as needed for Unscheduled timepoint
Concomitant medications/procedures	1	✔	23	23	23	To be invoiced as needed for Unscheduled timepoint
Physician - Per Hour	1	✔	104	104	104	To be invoiced as needed for Unscheduled timepoint
Study Coordinator - Per Hour	1	✔	41	41	41	To be invoiced as needed for Unscheduled timepoint

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Data Entry - Per Hour	1	✔	56	56	56	To be invoiced as needed for Unscheduled timepoint
Lactate dehydrogenase (LD) (LDH)	30	✔	14	14	420	To be invoiced as needed per Protocol and/ or for Unscheduled timepoint if not included in routine blood chemistry panel.
Collection of Biomarker samples: Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	1	✔	29	29	29	To be invoiced as needed for Unscheduled timepoint
Lab handling and/or shipping of Biomarker specimen(s): Peripheral Immunophenotyping, Cytokines, and/or ctDNA as required per protocol	1	✔	27	27	27	To be invoiced as needed for Unscheduled timepoint
Telephone evaluation	1	✔	52	52	52	If/as needed for Unscheduled Visit
Archived tumor tissue and/or bone marrow sample	1	✔	148	148	148	Invoice as needed, as required by protocol
Fine needle aspiration biopsy, including CT guidance; first lesion	3	✔	1.328	1.328	3.984	Invoice as needed, as required by protocol
Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	3	✔	403	403	1.209	Invoice as needed, as required by protocol
Ultrasonic guidance for needle placement	3	✔	319	319	957	Invoice as needed, as required by protocol
Tumor/lymph node biopsy	3	✔	1.010	1.010	3.030	Invoice as needed, as required by protocol
Anesthesia for intraperitoneal procedures in upper abdomen including laparoscopy; not otherwise specified	3	✔	596	596	1.788	Invoice as needed, as required by protocol
Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; not otherwise specified	3	✔	546	546	1.638	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Anesthesia for bone marrow aspiration and/or biopsy, anterior or posterior iliac crest	3	✔	320	320	960	Invoice as needed, as required by protocol
Bone marrow biopsy; by trocar or needle	3	✔	439	439	1.317	Invoice as needed, as required by protocol
Bone marrow aspiration, smear	3	✔	392	392	1.176	Invoice as needed, as required by protocol
Level IV - Surgical pathology, gross and microscopic examination: Includes examination and reporting:	3	✔	265	265	795	Invoice as needed, as required by protocol
Biopsy; Staining and preparation of the slides including shipping and handling	3	✔	124	124	372	Invoice as needed, as required by protocol
Coordination cost Physician: Pathology	3	✔	78	78	234	Purpose is for local Interpretation and report of slide and/or block.
FDG/PET or PET	14	✔	2.619	2.619	36.666	Invoice as needed, as required by protocol
Interpretation and Report; FDG/PET or PET	14	✔	227	227	3.178	Invoice as needed, as required by protocol
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	14	✔	616	616	8.624	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	14	✔	118	118	1.652	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	14	✔	574	574	8.036	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	14	✔	114	114	1.596	Invoice as needed, as required by protocol. Performed only if MRI is contraindicated.
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	14	✔	699	699	9.786	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	14	✔	135	135	1.890	Invoice as needed, as required by protocol
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	14	✔	652	652	9.128	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	14	✔	130	130	1.820	Invoice as needed, as required by protocol
Computed tomography, abdomen and pelvis; with contrast material(s)	14	✔	1.136	1.136	15.904	Invoice as needed, as required by protocol
Interpretation and Report; Computed tomography, abdomen and pelvis; with contrast material(s)	14	✔	208	208	2.912	Invoice as needed, as required by protocol
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	14	✔	786	786	11.004	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	14	✔	136	136	1.904	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	14	✔	671	671	9.394	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); with contrast material(s)	14	✔	131	131	1.834	Invoice as needed, as required by protocol
Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	14	✔	626	626	8.764	Invoice as needed, as required by protocol
Interpretation and Report; Computerized axial tomography, soft tissue of neck (Cat Scan) (CT Scan); without contrast material	14	✔	130	130	1.820	Invoice as needed, as required by protocol
Brain MRI with contrast	14	✔	1.162	1.162	16.268	Invoice as needed, as required by protocol
Brain MRI with Contrast: Interpretation and Report	14	✔	206	206	2.884	Invoice as needed, as required by protocol
Brain MRI without contrast	14	✔	1.084	1.084	15.176	Invoice as needed, as required by protocol
Brain MRI without Contrast: Interpretation and Report	14	✔	183	183	2.562	Invoice as needed, as required by protocol

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton): For Interpretation and Report use code R1551.	14	✔	1.281	1.281	17.934	Invoice as needed, as required by protocol
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	14	✔	196	196	2.744	Invoice as needed, as required by protocol
MRI, abdomen, abdominal (MRI); with contrast material(s)	14	✔	961	961	13.454	Invoice as needed, as required by protocol
Interpretation and Report; MRI, abdomen, abdominal (MRI); with contrast material(s)	14	✔	197	197	2.758	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
MRI, pelvis, pelvic (MRI); with contrast material(s)	14	✔	950	950	13.300	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; MRI, pelvis, pelvic (MRI); with contrast material(s)	14	✔	192	192	2.688	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
MRI, orbit, face and neck (MRI); with contrast material(s)	14	✔	1.089	1.089	15.246	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.
Interpretation and Report; MRI, orbit, face (MRI); with contrast material(s)	14	✔	319	319	4.466	Invoice as needed, as required by protocol. Performed only when CT is contraindicated. See respective protocol footnote for more detail.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
MUGA	1	✔	569	569	569	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
MUGA, Interpretation and Report	1	✔	114	114	114	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
ECHO	1	✔	261	261	261	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
ECHO, Interpretation and Report	1	✔	113	113	113	Invoice as needed, as required by Protocol. See respective protocol footnote for more detail.
Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy	14	✔	64	64	896	To be invoiced as needed when copies of diagnostic films are required
Coordination cost Nurse	4	✔	42	42	168	To be invoiced, as needed, for additional nurse time for inpatient Close Monitoring and/or treatment administration at C1D1. See Footnote 9 in Protocol for further details.
Overnight Facility Charge-Per Night	1	✔	1.414	1.414	1.414	To be invoiced, as needed, for Close Monitoring at C1D1 at the discretion of the PI. See Footnote 11 in Protocol for further details.Cannot be invoiced in addition to Hotel Stay per each occurrence.

Conditional Procedure	Max Qty	OH	Budget	Budget + OH	Budget Total	Comments
Hotel; Hotel stay per 24 hours, meals and transportation to/from site	1	✔	233	233	233	Alternative for patients dismissed from clinic who still need to be within 20 minutes of clinic in the event of CRS at C1D1. Cannot be invoiced in addition to Overnight Faciity Charge per each occurrence. **Applicable only for sites not using ClinCierge.**
Patient Reimbursement, Expenses, Patient Travel - Per Visit	31		30	30	930	Reimbursable as incurred, with receipts. **Applicable only for sites not using ClinCierge.**
CMV PCR	2	✔	64	64	128	As clinically indicated in addition to timepoints noted in Protocol
Gonadotropin; follicle stimulating hormone (FSH)	1	✔	46	46	46	Invoiceable if required at screening.
Infectious agent antigen detection; hepatitis B surface antigen (HBsAg)	1	✔	76	76	76	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C quantification; HCV RNA, quantification	1	✔	205	205	205	Invoiceable if required at screening.
Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification	1	✔	95	95	95	Invoiceable if required at screening.

Footnotes

1. Maximum quantity payable per site is the total quantity multiplied by the number of subjects actually enrolled.
2. The parties agree that they will discuss any units that exceed the cap in good faith, leveraging the EDC data. All agreed upon changes must be included in a contract amendment.
3. For time points where only Study Coordinator time is referenced - it is expected that the Study Coordinator will complete all needed data entry.
4. All safety labs are to be collected and analyzed locally.
5. PK and BioMarkers to be collected and shipped by site for central analysis.
6. Any items not covered in the site budget should be considered SOC.
7. Rituximab administration, via IV infusion or SC injection, is considered SOC and should be administered at timepoints noted in protocol. Dosing subsequent to C1D1 may be provided by either mode of administration.

See notes in Conditionals section for more details.

Site Cost	**Qty**		**Cost**	**Total**	**Comments**
Study Start-Up Fee/Site Set-Up One-time Fee (Trial revision , 500 euro, + art. 2 paragraphs 5 and 6 of DA/746. 2000 euros= 2500)	1		2.500	2.500	One time site payment
Pharmacy: Set-Up Fee (36 bags so 36 times, 100 euro each bags + 3 euro labelling for 36 bags is 103 x 36= 3708 euro)	1		3.708	3.708	One time site payment
Log and File Serious Adverse Event (SAEs) Reports/Forms: per incident	10		150	1.500	One time site payment per each quantity.
Document Storage, Archiving Total Cost	1		999	999	One time site payment
Pharmacy Close Out Visit	1		150	150	One time site payment
Pharmacy storage (for each arrival of drugs)	1		50	50	for each arrival of drugs
Pharmacy (monitoring visit)	1		100	100	for each monitoring visit
SIV visit (Pharmacy)	1		150	150	One time site payment
Ancillary Fees	1		644	644	One time site payment
Randomization fee	N/A		10		for each patient

Comparator/Rescue Medication Cost	**Qty**	**Budget**	**Total**	**Unit**
Human Serum albumin (HSA) 5% or 20% or 25% , **[ALBUMINA GRIFOLS , 50ML]**	as per protocol	21,89	21,89	per vial

AZIENDA OSPEDALIERA UNIVERSITARIA

PUBBLICAZIONE ALBO ONLINE

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